

be conducted pursuant to the provisions of section 431(a)(3) of the Act, including experimental projects for developing State leadership and the establishment of special services which hold promise of making a substantial contribution to the State educational agencies of all or several States. Such funds shall be administered by the receiving State on behalf of all of the participating States.

(20 U.S.C. 1831(b); 862(b)(2))

LOCAL EDUCATIONAL AGENCIES

§ 134b.40 Local educational agency activities.

(a) Funds available under § 134b.2(c) may be used to stimulate and assist local educational agencies in strengthening the leadership resources of their districts, and to assist those agencies in the establishment and improvement of programs to identify and meet the educational needs of their districts.

(20 U.S.C. 1831(b); 866(a))

(b) Activities authorized under paragraph (a) of this section may include:

(1) Educational planning on a district basis, including the identification of educational problems, issues, and needs in the district and the evaluation on a periodic or continuing basis of educational programs in the district;

(2) Providing support or services for the comprehensive and compatible recording, collecting, processing, analyzing, interpreting, storing, retrieving, and reporting of educational data including the use of automated data systems;

(3) Programs for conducting, sponsoring, or cooperating in educational research and demonstration programs and projects such as (i) establishing and maintaining curriculum research and innovation centers to assist in locating and evaluating curriculum research findings, (ii) discovering and testing new educational ideas (including new uses of printed and audiovisual media) and more effective educational practices, and putting into use those which show promise of success, and (iii) studying ways to improve the legal and organizational structure for education, and the management and administration of education in the district of such agency;

(4) Programs to improve the quality of teacher preparation, including student-teaching arrangements, in cooperation with institutions of higher education and State educational agencies;

(5) Programs and other activities specifically designed to encourage the full and adequate utilization and acceptance of auxiliary personnel (such as instructional assistants and teacher aides) in elementary and secondary schools on a permanent basis;

(6) Providing such agencies and the schools of such agencies with consultative and technical assistance and services relating to academic subjects and to particular aspects of education such as the education of the handicapped, the gifted and talented, and the disadvantaged, vocational education, school building design and utilization, school social work,

the utilization of modern instructional materials and equipment, transportation, educational administrative procedures, and school health, physical education, and recreation;

(7) Training programs for the officials of such agencies; and

(8) Carrying out any such activities or programs, where appropriate, in cooperation with other local educational agencies.

(20 U.S.C. 1831(b); 866(b))

COMPREHENSIVE PLANNING AND EVALUATION

§ 134b.50 Comprehensive educational planning and evaluation activities.

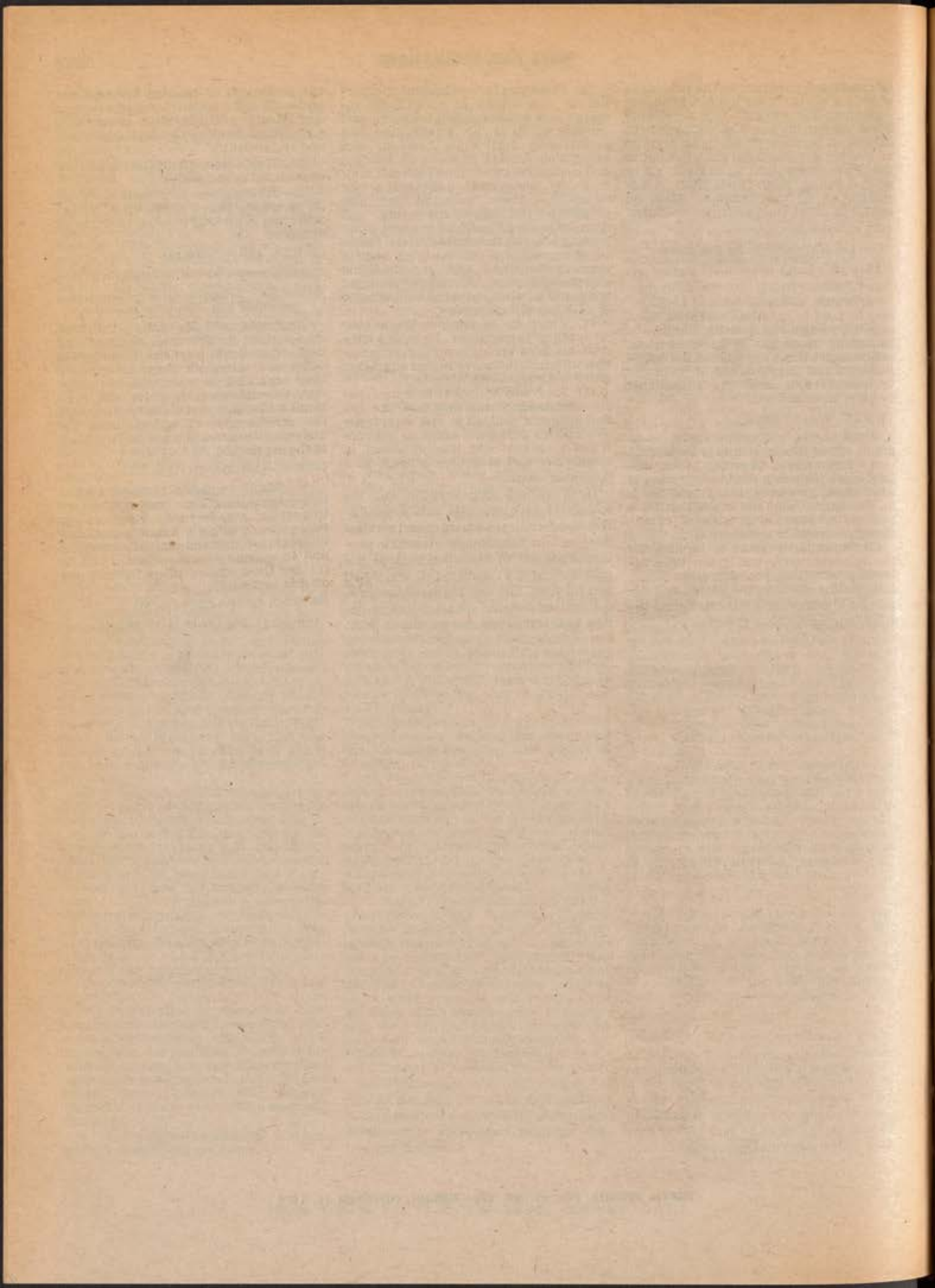
(a) Funds available under § 134b.2(c) may be used for activities by State and local educational agencies in order to assist and stimulate them to enhance their capability to make effective progress, through comprehensive and continuing planning and evaluation, toward the achievement of opportunities for high-quality education for all segments of the population.

(20 U.S.C. 1831(b); 867(a))

(b) Funds available to local educational agencies under paragraph (a) of this section may be used for demonstration projects to plan, develop, test, and improve planning and evaluation systems and techniques consistent with, and to further the purposes of, paragraph (a) of this section.

(20 U.S.C. 1831(b); 867a(b)(5))

[FR Doc. 75-30725 Filed 11-17-75; 8:45 am]





# **federal register**

**TUESDAY, NOVEMBER 18, 1975**



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**PART III:**

## **FEDERAL TRADE COMMISSION**

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### **PRESERVATION OF CONSUMERS' CLAIMS AND DEFENSES**

**Final Regulations, Proposed Amendment  
and Statement of Basis and Purpose**



Title 16—Commercial Practices  
CHAPTER I—FEDERAL TRADE  
COMMISSION

PART 433—PRESERVATION OF CON-  
SUMERS' CLAIMS AND DEFENSES

Promulgation of Trade Regulation Rule and  
Statement of Basis and Purpose

Notice is hereby given that the Federal Trade Commission, pursuant to the Federal Trade Commission Act, as amended, 15 U.S.C. 41, *et seq.*, the provisions of Part I, Subpart B, of the Commission's Procedures and Rules of Practice, 16 CFR 1.7, *et seq.*, and Section 553 of Subchapter II, Chapter 5, Title 5 of the U.S. Code (Administrative Procedure) has conducted a proceeding for the promulgation of a Trade Regulation Rule concerning Preservation of Consumers' Claims and Defenses. The proposed rule was published in the FEDERAL REGISTER for comments and hearings thereon on January 26, 1971 (36 FR 1211). A revised version thereof was published in the FEDERAL REGISTER for comments and hearings thereon on January 5, 1973 (38 FR 892).

Written comments from interested parties have been received by the Commission. Public hearings have been held in New York, New York (June 7-9, 1971); Chicago, Illinois (July 12-14, 1971); May 7-9, 1973; and Washington, D.C. (September 20-23, 1971 and March 12-15, 1973). See 36 FR 6592, 7865; and 38 FR 8600.

Accordingly, the Commission hereby amends Subchapter D, Trade Regulation Rules, Chapter I of 16 CFR by adding a new Part 433 as follows:

- Sec.  
433.1 Definitions.  
433.2 Preservation of consumers' claims and defenses, unfair or deceptive acts or practices.

AUTHORITY: 38 Stat. 717, as amended; (15 U.S.C. 41, *et seq.*)

§ 433.1 Definitions.

(a) *Person*. An individual, corporation, or any other business organization.

(b) *Consumer*. A natural person who seeks or acquires goods or services for personal, family, or household use.

(c) *Creditor*. A person who, in the ordinary course of business, lends purchase money or finances the sale of goods or services to consumers on a deferred payment basis; *Provided*, such person is not acting, for the purposes of a particular transaction, in the capacity of a credit card issuer.

(d) *Purchase money loan*. A cash advance which is received by a consumer in return for a "Finance Charge" within the meaning of the Truth in Lending Act and Regulation Z, which is applied, in whole or substantial part, to a purchase of goods or services from a seller who (1) refers consumers to the creditor or (2) is affiliated with the creditor by common control, contract, or business arrangement.

(e) *Financing a sale*. Extending credit to a consumer in connection with a

"Credit Sale" within the meaning of the Truth in Lending Act and Regulation Z.  
(f) *Contract*. Any oral or written agreement, formal or informal, between a creditor and a seller, which contemplates or provides for cooperative or concerted activity in connection with the sale of goods or services to consumers or the financing thereof.

(g) *Business arrangement*. Any understanding, procedure, course of dealing, or arrangement, formal or informal, between a creditor and a seller, in connection with the sale of goods or services to consumers or the financing thereof.

(h) *Credit card issuer*. A person who extends to cardholders the right to use a credit card in connection with purchases of goods or services.

(i) *Consumer credit contract*. Any instrument which evidences or embodies a debt arising from a "Purchase Money Loan" transaction or a "financed sale" as defined in paragraphs (d) and (e).

(j) *Seller*. A person who, in the ordinary course of business, sells or leases goods or services to consumers.

§ 433.2 Preservation of Consumers' Claims and Defenses, Unfair or Deceptive Acts or Practices.

In connection with any sale or lease of goods or services to consumers, in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, it is an unfair or deceptive act or practice within the meaning of Section 5 of that Act for a seller, directly or indirectly, to:

(a) Take or receive a consumer credit contract which fails to contain the following provision in at least ten point, bold face, type:

NOTICE

ANY HOLDER OF THIS CONSUMER CREDIT CONTRACT IS SUBJECT TO ALL CLAIMS AND DEFENSES WHICH THE DEBTOR COULD ASSERT AGAINST THE SELLER OF GOODS OR SERVICES OBTAINED PURSUANT HERETO OR WITH THE PROCEEDS HEREOF. RECOVERY HEREUNDER BY THE DEBTOR SHALL NOT EXCEED AMOUNTS PAID BY THE DEBTOR HEREUNDER.

or, (b) Accept, as full or partial payment for such sale or lease, the proceeds of any purchase money loan (as purchase money loan is defined herein), unless any consumer credit contract made in connection with such purchase money loan contains the following provision in at least ten point, bold face, type:

NOTICE

ANY HOLDER OF THIS CONSUMER CREDIT CONTRACT IS SUBJECT TO ALL CLAIMS AND DEFENSES WHICH THE DEBTOR COULD ASSERT AGAINST THE SELLER OF GOODS OR SERVICE OBTAINED WITH THE PROCEEDS HEREOF. RECOVERY HEREUNDER BY THE DEBTOR SHALL NOT EXCEED AMOUNTS PAID BY THE DEBTOR HEREUNDER.

Effective: May 14, 1976.

Promulgated by the Federal Trade Commission November 14, 1975.

CHARLES A. TOBIN,  
Secretary.

STATEMENT OF BASIS AND PURPOSE.

PREFACE

It is the Commission's purpose, in issuing this statement, to review thoroughly the information, data, and testimony which was received in the course of proceedings on this rule. It is also the Commission's purpose to state, with particularity, the purpose of each provision of the rule together with the Commission's reasons for adopting certain revisions as a result of information elicited during these proceedings.

The precise format of such statements may change from rule to rule, as a function of the complexity of the issues involved and the nature and extent of information received and evaluated.

CHAPTER I. HISTORY OF THE PROCEEDING

On January 21, 1971, the Commission announced a Trade Regulation Rule to Preserve Buyers' Claims and Defenses in Consumer Installment Sales.<sup>1</sup> The proposed rule was published in the FEDERAL REGISTER on January 26, 1971.<sup>2</sup> All interested parties were invited to file written data, views, or arguments concerning the proposed rule or to testify at public hearings in Washington, D.C., New York City,<sup>3</sup> and Chicago.<sup>4</sup>

As a result of the public record developed in the initial round of hearings, the Commission published a revised version of its proposed rule entitled Preservation of Consumers' Claims and Defenses on January 5, 1973.<sup>5</sup> In the reopened proceeding hearings were held in Washington, D.C.<sup>6</sup> and Chicago.<sup>7</sup> The closing date for written comments and submissions was June 11, 1973.<sup>8</sup>

In the course of two rounds of hearings on this rule, conducted by the Assistant Director for Rulemaking,<sup>9</sup> every person who expressed a desire to present his views had an opportunity to do so. The 2,250 page transcript of the hearings has been included in the public record of these proceedings, together with 7,362 pages of written comment.<sup>10</sup> In this Statement references to the transcript of hearings are designated by the prefix "Tr." References to written submissions on the record are designated by the prefix "R".

As a result of the information, testimony, and data elicited in the course of proceedings on this rule, the Commission has concluded that final enactment of a revised version of the rule would be in the public interest. The final revisions are fully explained herein below and supported by substantial evidence on the record of this proceeding.

Accordingly, pursuant to Section 6(g) of the Federal Trade Commission Act together with Section 202 (c) of the Federal Trade Commission Improvements Act (Public Law 93-637, January 4, 1970), the Commission herewith announces final adoption of its Trade Regulation Rule pertaining to Preservation of Consumers' Claims and Defenses in credit-sale transactions. This Statement of Basis and Purpose is published to

See footnotes at end of chapter.



define, with particularity, the reasons the Commission has decided to take this action together with the purposes of the rule.

<sup>1</sup> FTC News Release of January 21, 1971.

<sup>2</sup> 36 FR 1211.

<sup>3</sup> 36 FR 7865 (April 27, 1971). Washington hearings were originally scheduled to begin May 10, 1971, but were rescheduled and held September 20-23, 1971.

<sup>4</sup> 36 FR 6592 (April 7, 1971). Hearings were held in New York on June 7-9, 1971 at the Federal Building, 26 Federal Plaza (Foley Square).

<sup>5</sup> 36 FR 7865 (April 27, 1971). Hearings were held in Chicago on July 12-14, 1971 at the Everett Dirksen Building.

<sup>6</sup> 38 FR 892.

<sup>7</sup> March 12-15, 1973.

<sup>8</sup> 38 FR 8600 (April 4, 1973). Hearings were held May 7-9, 1973 at the La Salle Hotel.

<sup>9</sup> 38 FR 8600 (April 4, 1973).

<sup>10</sup> Pursuant to Commission Directive, 35 FR 15164.

<sup>11</sup> F.T.C. File 215-31.

## CHAPTER II. BACKGROUND

**General introduction.** In 1971, the year this proceeding was commenced, aggregate consumer installment debt in the United States amounted to 137.2 billion dollars.<sup>1</sup> This figure represented a five-fold increase in outstanding consumer credit from the year 1950, for a compound annual growth rate, over the 21 year period of 9 percent.<sup>2</sup> Forty-eight percent of all U.S. families allocated some 14.7 percent of all U.S. disposable personal income to the repayment of installment obligations.<sup>3</sup> By 1974, aggregate installment indebtedness had increased to 154.5 billion dollars, a large part of which was employed in the acquisition of consumer goods and services.<sup>4</sup>

Over the past two decades, banks and credit unions have vigorously pursued emerging opportunities in the consumer credit market. They held 54.4 billion dollars in consumer installment credit as of December 1970, or 53.8% of the market. In December 1950, commercial banks and credit unions held only 6.3 billion dollars in consumer installment credit.<sup>5</sup> Manufacturers of automobiles and other "large ticket" items in the consumer inventory have created huge consumer finance subsidiaries to meet the needs of both dealers and consumers. At the same time, large independent consumer finance companies have experienced equally prodigious growth in servicing demand from consumers who do not or cannot obtain bank credit. Finally, the larger retail establishments have created credit departments and subsidiaries to service customers at the same location where purchases are made.<sup>6</sup>

Credit institutions have thus become active, and frequently dominant, partners in the retail distribution of consumer goods and services. In many instances, they finance dealers and consumers alike, extending credit for the acquisition of inventory and receiving increased "acceptance" or "discount" business from the dealer as his business grows.<sup>7</sup> Where smaller retailers lack the resources or volume to justify a credit subsidiary or a continuing relationship

with an acceptance company, it is not uncommon for them to enter into one or more formal or informal arrangements with consumer finance outlets serving their community. Buyers may be referred for loans to a cooperative consumer finance company on a more periodic basis.

As of August, 1974, finance companies, retailers, and other financial institutions which are directly subject to the Federal Trade Commission's jurisdiction held in excess of 75 billion dollars in consumer installment debt.<sup>8</sup> This constitutes a major commitment to the retailer market on the part of these institutions. It is this major commitment, together with widespread evidence of abuse and injury discussed below in this *Statement*, which suggests a need for this rule. The rule is directed at what the Commission believes to be an anomaly. To a varying extent, depending on the jurisdiction where a credit sale is completed and the procedure employed to execute the sale, the party financing the transaction is able to assert rights which are superior to those of the seller. The creditor may assert his right to be paid by the consumer despite misrepresentation, breach of warranty or contract, or even fraud on the part of the seller, and despite the fact that the consumer's debt was generated by the sale.

**How sellers separate the consumer's duty to pay from the seller's duty to perform.** There are two methods of eliminating creditor exposure to consumer claims or defenses arising from a credit sale. In the first case the seller is the initial creditor. He executes a retail installment sales agreement with his buyer, together with a promissory note where this is permitted, and he then sells (discounts) the contract and/or note to a sales finance company or a bank. In the second case the seller acts as a conduit, referring his buyers to local consumer finance outlets for personal loans, the proceeds of which are then applied to cash purchases. Where the arranged loan is used, the goods purchased are usually collateral for the debt.

**Installment sales transactions: The discount method.** Sellers and creditors may succeed in insulating the creditor's claim to repayment from any and all seller misconduct in the underlying transaction by compelling the consumer buyer to enter the commercial paper market. This is accomplished by the use of promissory notes, in the sales finance component of the transaction, or by the incorporation of a waiver of defenses clause in a retail installment sales contract.

The use of a promissory note entails the execution and subsequent assignment of what commercial law calls a "negotiable instrument." Under Article Three of the Uniform Commercial Code, pre-existing equities are foreclosed when a negotiable instrument is purchased by a third party in good faith and without notice of claims, defenses, or infirmities arising from the transaction between the makers. When a third party purchases a consumer's promissory note, he will receive the note as a "holder in due course"

free and clear of any claim or grievance that the consumer may have with respect to the seller. He may claim and receive payment notwithstanding anything that may have been done or said by the seller in the prior transaction which spawned the note, provided he has no knowledge of seller misconduct.

The definition of "holder in due course" which appears in Article Three of the UCC is a recapitulation of principles which were first articulated in *Miller v. Race*, 97 Eng. Rep. 398 (K.B. 1758). To protect the burgeoning commercial paper market the court in *Miller* decided that a bona fide purchaser of an instrument which was negotiable on its face should not be required to look behind the face of the obligation. A promissory note drawn on the bank of England was stolen and subsequently sold to a legitimate merchant. The court determined that the draft should be treated as money, and that the bona fide purchaser who had no notice of the history of the note would prevail over all other claimants. The rationale behind this decision was the social utility to be obtained from a system which encouraged and protected commercial transactions. If businessmen were required to look behind an instrument which on its face was negotiable, the soundness of the entire commercial system would be threatened. At that time promissory notes drawn on the bank of England were not "legal tender." Like modern day bank drafts, they changed hands frequently and rapidly and served many of the functions served by specie. These same principles underpinned the English Bills of Exchange Act of 1882 and the Uniform Negotiable Instruments Law enacted in this country in 1896. The Uniform Commercial Code superseded the Negotiable Instruments Law.

Over two centuries, the holder in due course doctrine has served the two-fold interest of liquidity and confidence in the commercial paper market.<sup>9</sup> The term negotiable instrument has come to encompass a variety of short and long term obligations. Included are checks, banker's acceptances, bills of exchange, letters of credit, bills of lading, and promissory notes. Each of these devices has a variety of commercial applications. Each is technically different from the rest, but all have one essential feature in common. They contain an "unconditional promise or order to pay a sum certain in money and no other promise, order, obligation, or power. . . ."<sup>10</sup>

While the principles articulated in *Miller v. Race* have validity in commercial exchanges and transfers, their application to consumer credit sales is anomalous. Consumers are not in the same position as banks, bond issuers, or shippers of freight; nor are they in an equivalent position to vindicate their rights against a payee. The considerations which underpin the laws of negotiability have little or no application in consumer transactions where the integrity of the commercial paper market is not a concern. Unfortunately, where promissory notes are employed in connection with credit sales, consumers are forced

See footnotes at end of chapter.



to enter this market. The average consumer would hardly expect that his sales agreement will receive the same treatment as a sight draft on the Bank of England, in the event that his seller fails to perform as promised. This result is nonetheless assured. When an acceptance company purchases a consumer's promissory note and sends a payment book in the mail, it can assert rights which are superior to those of the seller. For the consumer to defeat the creditor's right to be paid in the face of gross seller misconduct, he must prove that the creditor holding the note had actual knowledge of seller abuse in the prior transaction. Where a negotiable instrument is employed in a consumer transaction, defeating holder in due course status is always difficult and often impossible.<sup>11</sup>

Where law or commercial expediency forbid the use of promissory notes in consumer sales, creditors and sellers still have an indirect procedure for accomplishing the same end. An assignee of a retail installment contract, as distinguished from a note because of the inclusion of mutual promises and obligations, may, under UCC 9-206, assert rights analogous to those of a holder in due course if the contract contains an "agreement not to assert defenses against an assignee."<sup>12</sup> Creditor and seller need only insert a waiver of defenses clause in the consumer's sales agreement with the seller. If the same tests of good faith and lack of notice are met, the creditor who buys the contract is in the same position as a holder in due course.

*State law affecting the discount method.* Some forty jurisdictions have enacted legislation bearing on foreclosures of equities in installment sales. Existing enactments fall into two categories. The first category consists of statutes which render "holder in due course" principles inapplicable in consumer sales transactions.<sup>13</sup> Such enactments prevent the use of negotiable instruments in credit sales, but often have no effect on the continuing use of a waiver of defenses to achieve the same result. The second category consists of "complaint period" statutes which restrict cut-offs of consumer rights for a stated time period during which the consumer is permitted, after receipt of notification that his obligation has been assigned to an acceptance company, to communicate sale-related grievances directly to the creditor.<sup>14</sup> Any claim or defense which is raised during this time may be asserted in a subsequent suit to defeat or diminish a creditor's claim for payment.

The original draft of the Uniform Consumer Credit Code (UCC) reflected both of these approaches. It invalidated the use of negotiable instruments in sales transactions. This prohibition was followed by two alternative approaches to waivers of defenses, designated alternative A and alternative B. Under alternative A, waivers of defenses were flatly prohibited. Under alternative B, a ninety-day complaint period was provided. Enacting states were free to select

between the two alternative approaches to waivers. Of seven enacting jurisdictions all selected alternative B, and several reduced the length of the complaint period substantially.<sup>15</sup> Mounting criticism of the complaint period approach and unsatisfactory experiences in complaint period jurisdictions have induced the draftsmen of the revised UCC to delete alternative B.<sup>16</sup>

In addition to legislative enactments, judicial decisions in some jurisdictions have mitigated harsh applications of the law of negotiability in certain specific cases. Creditors have been held to share a sufficient community of interest and endeavor to persuade some jurists that "knowledge" should be imputed to the creditor or that the creditor should be liable as a primary party to the transaction.<sup>17</sup> The common law doctrine of unconscionability has also been used to set aside oppressive instances of boilerplate waivers of defenses on similar grounds.<sup>18</sup>

More recently, certain state courts have undertaken a frontal assault on the law of negotiability as it pertains to consumer transactions. These decisions suggest mounting expert opinion that commercial banking doctrines have no place in retail sales. The Georgia Court of Appeals recently held that retail installment contracts will no longer be treated as negotiable instruments.<sup>19</sup> The Florida courts have invalidated the use of boilerplate waivers of defenses;<sup>20</sup> and the California Supreme Court has extended application of a recent legislative enactment to place consumers in an offensive position, permitting the assertion of claims and defenses whether or not a creditor files suit for payment.<sup>21</sup>

These developments have had significant impact on the continuing vitality of these principles of law. They reflect widespread public concern about mechanical abrogations of consumer rights.<sup>22</sup> Unfortunately, holder in due course principles still affect consumers in many jurisdictions. As detailed below, the hearings and written submissions received in the course of this three-year proceeding reveal a continuing need for meaningful Federal intervention.

*Vendor-related loans.* The second alternative which is available to sellers and creditors is the direct personal loan. After a buyer selects an item for purchase and requests credit terms, the seller may refer the buyer to a local loan outlet. Referral can and does include accompanying the buyer to the loan office, remaining present while applications are processed and accepting a loan proceeds check endorsed to both seller and buyer. For this reason, this practice has been referred to as body-dragging.

The law continues to regard a pre-arranged loan of this kind as indistinguishable from a spontaneous transaction solicited by a borrower. The existence of a formal or informal business relationship between seller and lender does not alter this fact. Despite continuing referrals, affiliation, or even actual knowledge on the lender's part that the

seller engages in questionable sales practices, the loan and sale transactions continue to receive discrete treatment. The lender's claim for repayment remains wholly independent of any sales agreement between borrower and seller. The vendor-related loan thus presents a convenient alternative to discount financing. Issues such as knowledge, community of interest, or bad faith never arise. The hearings and written submissions received in the course of this proceeding indicate that substantial increases in body-dragging have been spawned by state enactments abrogating holder-in-due-course law. This fact is directly reflected in the recent Massachusetts enactment which was drafted to cover related-lender financing.<sup>23</sup>

Direct loan financing is discussed in detail below, at Chapter IV. Suffice it to say at this point that this type of financing offers a viable alternative to the discount method, one which has proved increasingly attractive in jurisdictions where the discount method has been restricted.

*The balance of this statement.* The remainder of this Statement of Basis and Purpose is devoted to a discussion of the information obtained in the course of proceedings on this rule, the conclusions drawn by the Commission after review of the record, and an exegesis of the nature and purpose of the rule which we have prepared to deal with a nationwide problem. Our reasons for selecting a particular approach in lieu of others which were suggested in the course of these proceedings are fully explained.

<sup>1</sup> *Consumer Credit in the United States*, Rept. of the National Commission on Consumer Finance 5 (December, 1972) (hereinafter *NCCF Rept.*).

<sup>2</sup> *Id.*

<sup>3</sup> *NCCF Rept.* at pages 16-17.

<sup>4</sup> *Fed. Res. Bull.*, Vol. 60, No. 10 at A-47 Oct. 1974.

<sup>5</sup> *NCCF Rept.* at page 11.

<sup>6</sup> As of December 1970, retailers held 14.1 billion dollars in installment credit or 13.9% of the market.

<sup>7</sup> In August, 1974, consumer finance companies held 38.9 billion dollars in installment credit. *Fed. Res. Bull.* *supra* note 15, at A-47, A-48. This prodigious sum may be contrasted with the 5.3 billion dollars they held in December, 1950. *NCCF Rept.* at 11.

<sup>8</sup> This figure is derived from subtracting the 73.3 billion in installment credit held by commercial banks which are exempt from 15 U.S.C. 41 *et seq.* from the 154.5 billion outstanding as of August, 1974. *Fed. Res. Bull.*, *supra* note 15.

<sup>9</sup> See Littlefield, *Good Faith Purchase of Consumer Paper*, 39 *Southern Cal. L. Rev.* 48 (1966).

<sup>10</sup> Uniform Commercial Code Sec. 3-104.

<sup>11</sup> Note, "Consumer Financing, Negotiable Instruments, and the Uniform Commercial Code: A solution to the Judicial Dilemma", 55 *Cornell L. Rev.* 611 (1970); Comment, "Judicial and Statutory Limitations on the Rights of a 'Holder in Due Course' in Consumer Transactions", 11 *B.C. Ind. & Comm. L. Rev.* 90 (1969); Comment, "The Role of Cut-Off Devices in Consumer Financing", 1968 *Wisc. L. Rev.* 505; Comment, "Financing Consumer Goods Under the Uniform Commercial Code: Installment Buyers



and Defaulting Sellers", 37 U. Chi. L. Rev. 513 (1970).

"The following is an example of a typical waiver of defense clause:

"If the seller should assign the contract in good faith to a third party, the buyer shall be precluded as against such third party from attacking the validity of the contract on grounds of fraud, duress, mistake, want of consideration. . . ."

NCCP Rept. at 34-35.

"E.g., Md. Ann. Code art. 83, § 147 (1968); Mass. Gen. Laws Ann. ch. 225, § 12C (1968); Vt. Stat. Ann. tit. 9, § 2455 (Supp. 1968); Rev. Code Wash. Ann. tit. 63, § 14.020 (Supp. 1968).

"E.g., Del. Code Ann. tit. 6, § 4312 (Supp. 1966) (15 days); Ill. Rev. Stat. Ch. 121 1/2, § 262D (Smith-Hurd Supp. 1968) (5 days). See also Murphy, "The Consumer and the Code: A Cross-sectional view", 23 Univ. of Miami L. Rev. 11, 65 (1968); C. Katz, ed., *The Law and the Low Income Consumer* 249-51 (1968).

"CCH Consumer Credit Guide Paragraph 5104: "Local Modifications".

"Murphy, "Lawyers for the Poor View the UCC", 44 N.Y.U. Rev. 298, 315 (1969).

"E.g., Commercial Credit Corp. v. Childs, 199 Ark. 1073, 137 S.W. 2d 260 (1940); Commercial Credit Corp. v. Orange County Mach. Works, 34 Cal. 2d 766, 214 p. 2d 819 (1950) Mutual Fin. Co. v. Martin, 63 So. 2d 65 (Fla. 1953).

"Unico v. Owen, 50 N.J. 101, 232 A.2d 405 (1967).

"Geiger Finance Co. v. Graham, 123 Ga. App. 771, 182 S.E.2d 621 (1971). This case is discussed in a *Georgia State Bar Journal* 400 (Feb. 1972).

"Rehurek v. Chrysler Credit Co., 262 so. 2d 452 (1972).

"Vasquez v. Superior Ct. of San Joaquin County, 4 Cal. 3d 800, 823; 484 P. 2d 964, 979 (1971).

"See, e.g., Wallace, "The Logic of Consumer Credit Reform," 82 Yale L.J. 461 (1973); Note, "Direct Loan Financing of Consumer Purchases," 85 Harv. L. Rev. 1409 (1972); Note "Consumer Financing, Negotiable Instruments, and the Uniform Commercial Code: A Solution to the Judicial Dilemma," 55 Cornell L. Rev. 611 (1970); Comment, "Financing Consumer Goods Under the Uniform Commercial Code: Installment Buyers and Defaulting Sellers," 37 U. Chi. L. Rev. 513 (1970); Comment, "Judicial and Statutory Limitations on the Rights of A Holder in Due Course; in Consumer Transactions," 11 B.C. Ind. & Comm. L. Rev. 90 (1969); Littlefield, "Preserving Consumer Defenses: Plugging the Loophole in the New U.C.C.C." 44 N.Y.U.L. Rev. 272 (1969); Kripke, "Consumer Credit Regulation: A Creditor-Oriented Viewpoint," 68 Colum. L. Rev. 455, 459-473 (1968); Comment, "Consumer Protection—The Role of Cut-Off Devices in Consumer Financing," 1968 Wisc. L. Rev. 505; Symposium on Consumer Credit "Developments in the Law: Finance Companies and Banks as Holders in Due Course of Consumer Installment Credit Paper," 55 Nw. U. L. Rev. 339 (1961); Gilmore, "The Commercial Doctrine of Good Faith Purchase," 63 Yale L.J. 1057, 1097-1100 (1954); Kripke, "Chattel Paper as a Negotiable Specialty Under the Uniform Commercial Code," 69 Yale L.J. 1209, 1215-1216 (1950).

"Gen. Laws Mass. Ch. 255D, § 22A.

# CHAPTER III. COMMISSION FINDINGS WITH RESPECT TO THE USE OF NEGOTIABLE INSTRUMENTS AND WAIVERS OF DEFENSES IN CONSUMER INSTALLMENT SALES TRANSACTIONS

This chapter discusses the Commission's findings with respect to fore-

See footnotes at end of chapter.

closures of consumer claims and defenses in sale transactions. We will concentrate on installment sales, where a promissory note or a waiver of defenses insulates the creditor from seller misconduct. Arranged loans will be discussed in Chapter IV.

Criticism of application of the holder in due course doctrine to consumer transactions has concentrated on the fact that it places the risk of a seller's misconduct on the party least able to bear the burden—the individual consumer. It also enables a merchant who engages in disreputable and unethical sales practices to establish and maintain a source of payment which assures him a place in the market, notwithstanding continuing breaches of contract and warranty. The relatively equal bargaining power which characterizes dealings between merchants is absent in consumer transactions, which are consummated by the use of standard form contracts which the customer must sign as a condition of purchase. Consumers without sufficient resources or business sophistication are frequently unable to press their claims effectively against dishonest sellers;<sup>1</sup> moreover, the seller may be beyond the reach of an effective remedy.<sup>2</sup> Because he is prevented from asserting the seller's breach of warranty or failure to perform against the assignee of the consumer's instrument, the consumer loses his most effective weapon—nonpayment.

Between an innocent consumer, whose dealings with an unreliable seller are, at most, episodic, and a finance institution qualifying as "a holder in due course," the financier is in a better position both to protect itself and to assume the risk of a seller's reliability. The financier may have recourse against the seller based on the seller's endorsement of the instrument, or it may have a full recourse agreement with the seller and withhold part of the payments to the seller as a reserve.<sup>3</sup> In addition, financial institutions usually protect themselves by warranties from the merchant as to freedom of the obligation from customer defenses.<sup>4</sup> As the National Commission on Consumer Finance recognized, financial institutions which purchase consumer paper are in a better position to control the credit practices of retail merchants:

"They can choose the retailers and suppliers with whom they will do business. If a financial institution is subject to consumers' defenses against payment, such as failure of consideration, nondelivery, etc., it will discontinue purchase of paper from those merchants who cause trouble thereby forcing the many merchants who desire to stay in business but need financial institutions to buy their consumer credit paper to 'now react responsibly to consumer complaints in order to keep the avenue of credit open.'"

The foregoing discussion suggests that waivers of defenses and promissory notes which result in foreclosures of substantial pre-existing equities between parties to a transfer of money have little or no place in consumer transactions. The insulation obtained by creditors in consumer transactions is the product of an inappropriate application of legal principles developed by and for merchants and

bankers. The following example, drawn from the transcript of the New York Hearings, is included as an illustration:

*Interpreter:* Mr. Suarez says, my name is Jose Suarez and I live on Westchester Avenue, the Bronx. I don't know how to write or speak English.

On or about December 29, 1970 two salesmen visited at my home; one of them Spanish speaking asked me if I knew how to talk English. I answered that I didn't and he asked me would I like to learn. I answered that I would and they came into my house. The Spanish speaking salesman told me that his name was Mr. Hernandez and started talking about English language lessons. Mr. Hernandez explained that this course was composed of records, lessons and some tapes that I will have to record in my voice and send to Columbia Institute for some teachers to go over. He told me that it would be very easy to learn English with this method.

He also showed to me some drawings of the equipment. This looked like big equipment. Mr. Hernandez told me that the price of the course was \$483.

Mr. Hernandez gave me a contract to sign, but since this contract was in English I could not read it. He repeated that the price was \$483 to be paid in installments of \$24. I gave him \$15 as a down payment and I signed the contract.

Two or three weeks after this I received the same equipment. This was not what I expected. It was a small tape recorder and I didn't know how to use it. I have not been able to use it.

Shortly after this a friend of mine who knows how to read English saw the contract and told me that I was owing them almost \$500. When I learned that I tried immediately to get in touch with Mr. Hernandez. I called the telephone number that was printed on the contract. The person with whom I talked told me that Mr. Hernandez had another telephone number and she gave it to me. I have been calling there several times and Mr. Hernandez is never available. I think that once Mr. Hernandez answered the phone but he lied and he told me he was another person.

Meanwhile I stopped payments because this was the only way I would make them hear my case.

Two months ago I started receiving letters from Lincoln Budget telling me that I owed them money. I thought I had to pay to Columbia and I didn't know I had to pay to another company.

More or less at the time a person went to my place of work and asked me why I was not paying. I explained the problem. I explained why I stopped payments and I told him that I wanted to talk to Mr. Hernandez. This person told me that I had to pay and that we would see each other in court.

More or less by April 10th I received another letter from Lincoln Budget telling me that this was going to be in court.<sup>5</sup>

The experience related above contains many of the problems arising from application of the holder in due course doctrine to consumer transactions. From analysis of the record, the Commission finds:

(1) That sellers and creditors frequently subject consumers to foreclosures of sale-related equities in the course of effectuating credit sales.

In the proceedings conducted pursuant to the proposed rule no witnesses—not even industry spokesmen—suggested that application of the holder in due course doctrine to consumer sales never results in the loss of legitimate consumer



claims, although some maintained that the problem was insignificant. The major issue, therefore, is whether the frequency of such occurrences indicates that action is desirable.

The record contains over fourteen thousand indications of foreclosures of asserted claims and defenses in credit sale transactions. There are over one hundred cases represented by consumer histories provided spontaneously for this proceeding—both in written submissions<sup>8</sup> and in oral testimony at public hearings.<sup>9</sup>

The magnitude of the problem is made clear through the aggregate statistics supplied by various consumer groups,<sup>10</sup> legal aid agencies<sup>11</sup> and the Office of Economic Opportunity.<sup>12</sup> Statistics compiled by the Office of Economic Opportunity (OEO) are especially noteworthy.

At the request of the Commission, the OEO Office of Legal Services polled its neighborhood legal services projects on the incidence of consumer injury arising from the use of negotiable notes and waiver of defense agreements. OEO arranged for a survey to be conducted by an outside service, the Bureau of Social Science Research, Inc. The survey results from the backbone of the record demonstrating the magnitude of consumer injury spawned by the two cut-off devices.<sup>13</sup>

The survey reflected the results of detailed returns from 59 projects in 32 states and territories, and from each of the ten OEO regions. The 59 projects "include very large and very small projects operating in both urban and rural areas [and] . . . during the year closed, in the aggregate, 179,314 cases. This number is nearly one-fourth (23.9 percent) of the total projected Legal Services Projects caseload for the current fiscal year (750,000 cases)."<sup>14</sup> Thus, the OEO sample is large and varied enough to permit generalization as to the contours of the problem.

#### The analysis reports:

The same 59 projects, handled a total of 13,781 holder in due course and waiver of defenses cases, or combinations thereof, during the period [May 1, 1970 to April 30, 1971]. Thus, these cases comprised 7.7 percent of their aggregate caseloads. Or, to put it in another way, one out of every 13 cases involved holder in due course or waivers of defenses. Considering the great variety of types of civil cases handled by Neighborhood Legal Services Offices, this would appear to be a rather heavy concentration for a single pair of related types.

Of the three possibilities—holder in due course, waiver of defenses and the combination of the two—cases involving holder in due course are by far the most common . . .

TABLE 1.—Distribution of types of cases

Type of case	Number	Percent
Holder in due course	10,122	73.5
Waiver of defense	1,094	7.9
Combination	2,565	18.6
Total	13,781	100.0

See footnotes at end of chapter.

Holder in due course is involved in 92.1 percent of all these cases, including the "combination" cases; waiver of defenses is involved in . . . 26.5 percent, again including "combination" cases.<sup>15</sup>

In assessing the OEO figures it is important to keep several points in mind. First, although the problems associated with the holder in due course doctrine are most keenly felt by the poor in our society, the OEO statistics—which are drawn from the legal projects' lower income clientele—do not represent their full extent. Such problems are not limited to the poor.

Secondly, not all persons, rich or poor, are knowledgeable enough to seek legal aid when confronted with a "holder" or waiver problem. In general, the number of persons seeking the aid of Neighborhood Legal Services agencies is only a fraction of those with legal problems.<sup>16</sup> Therefore, only a fraction of the low-income consumers wronged by cutoff devices show up in caseload statistics. In short, "[the] magnitude of the problem indicated by this sample is frightening."<sup>17</sup>

In addition to the statistics just summarized, the record contains testimony and written comment of a more general nature, yet from authoritative sources. Individuals, state agencies and legal aid groups submitted comments which contained information concerning consumer injury from foreclosures of rights in generalized or summary fashion. Much of this information was submitted by persons highly qualified to draw just such generalizations.<sup>18</sup>

#### From the hearings, for example:

I am an associate judge of the Circuit Court of Cook County. From September [1970] through April, 1971 I heard and disposed of over 3,000 cases involving . . . creditors actions.

I use the words "vast majority." I keep statistics on dispositions but I don't keep statistics on what proportion are plaintiffs and who they are, but I would say a very, very large number are brought on behalf of finance institutions [as holders in due course] . . . Many of the businesses are no longer available . . . They have their money so they are not interested in pursuing it any further . . .

I remember last year we had quite a surge of health club contract suits . . .

We had many of these refrigerator and meat franchises where the meat is substandard in quality or not of the type ordered, things of that nature. It's a breach of warranty argument. We see it quite often. I, again, have not kept statistics on it.<sup>19</sup>

The written record also contains comments of a more general nature. For example, "Though statistics are not available as to the exact percentage [of 585 consumer complaints received by the Wisconsin Attorney General's Office of Consumer Protection in 1969] which involved a financing arrangement with an alleged holder in due course, a significant proportion did."<sup>20</sup>

Similarly, "of the hundreds of consumer cases handled yearly by our offices a very significant majority involve installment sales transactions out of which develop a number of defenses which could be raised against the seller, but which are effectively lost through the

negotiation or assignment of the instrument evidencing the sale to a so-called holder-in-due-course."<sup>21</sup>

Thus, in both specific cases and generalized yet authoritative testimony, the record solidly establishes the magnitude of consumer injury arising from the use of promissory notes and waivers of defenses in credit sale transactions.

(2) That sellers and creditors rely on such cutoff devices in a wide variety of consumer transactions.

Having established the magnitude or extent of consumer injury from forfeited claims and defenses in credit sale transactions, the Commission requested and received specific information as to the areas or sectors of retail sales endeavor where such injury appeared to be most prominent. This inquiry was initiated to determine whether or not a rule could be prepared along narrow lines to delineate those areas where relief was most needed, without unduly affecting sectors of the retail market where foreclosures of equities might have some commercial utility. The record is overwhelmingly suggestive of the need for across-the-board relief. While the most serious instances of foreclosure of asserted claims would appear to be found in the most marginal sales transactions (e.g., inner-city door-to-door-sales), the simple range of transactions brought to the attention of the Commission in actual case histories precludes any effort at narrowing or delineation along the lines discussed above. Creditors and sellers rely on devices to insulate the creditor from consumer claims and defenses in a complex and extensive variety of retail transactions.

Among the types of consumer goods or services involved in the case histories on the record are:

**Courses of training or instruction.** The most notable development in this category was a large number of cases in which the holder in due course doctrine or waivers of defenses figured in health club or so-called "health spa" deceptions.<sup>22</sup>

One case involves 1,500 families.<sup>23</sup> The Missouri, Tr. 600-610 R. 1243-1258.

fact that so many of the health spa operations have used negotiable instruments or waivers of defenses is strong reason to refrain from limiting the scope of the rule to specified consumer sales. It affords evidence that these techniques are seized upon by those who set out to exploit new fields of consumer fraud and deception.

Other cases brought to our attention include courses of English language instruction,<sup>24</sup> television and modeling school courses<sup>25</sup>, computer schools,<sup>26</sup> flying lessons,<sup>27</sup> a karate school,<sup>28</sup> and other miscellaneous courses of training or instructions.<sup>29</sup>

**Furniture and appliances.** Many consumers indicated they were unable to assert defenses (such as the seller's failure to deliver or refusal to honor warranties or service agreements, delivery of shoddy or inferior goods or items other than those picked by the consumer) against third-party finances of pur-



chases in the furniture and appliance category. Cases frequently involved televisions and stereo sets.<sup>20</sup> Other cases concerned furniture,<sup>21</sup> a washing machine,<sup>22</sup> sewing machines,<sup>23</sup> curtains<sup>24</sup> and miscellaneous items.<sup>25</sup>

**Home improvements.** Home improvements have long been an area subject to considerable deception and outright fraud.<sup>26</sup> In one especially outrageous scheme, which cost hundreds of homeowners millions of dollars, a few homeowners' suits are finally being heard in the courts. Because the contractor has become bankrupt, however, and because consumers cannot maintain claims or defenses against holders in due course of their negotiable instruments, consumers who are fortunate enough to obtain favorable judgments in court will receive only about five cents on the dollar when the remaining meager assets of the contractor are distributed to satisfy debts and judgments.<sup>27</sup>

A related field of deception is the sale of aluminum siding.<sup>28</sup> The record reflects numerous cases of abuse in siding sales and subsequent collection efforts by third party holders of promissory notes.<sup>29</sup> Such sales occur nationwide, often involve a referral scheme or "model home" ploy and invariably produce substantial indebtedness for the consumer.<sup>30</sup>

**Freezer meats and other food plans.** This is an area of longstanding abuse.<sup>31</sup> Typically, the consumer is led to believe that a food or meat supply plan is being purchased.

In fact, the consumer is buying a freezer, often at grossly inflated cost,<sup>32</sup> and with no assurance that food will continue to be supplied. Frequently the consumer finds that the quality of food actually received is inferior, that the monthly shipments soon cease, and that his contract has been negotiated to a third party who insists on payment.<sup>33</sup>

**Automobiles.** Automobile sales often resulted in cases on the record in which the promissory notes or other cut-off devices were invoked to defeat assertion of seller-related defenses by the purchaser of the car.<sup>34</sup> Several state statutes restricting this practice are expressly limited to auto sales.<sup>35</sup> The abuses arise about twice as often with used cars as with new.<sup>36</sup> One of the most egregious cases on the record, however, concerns an expensive, brand-new specialty car.<sup>37</sup>

**Carpeting.** Carpet sales are another area in which substantial consumer injury has been documented. Sellers of carpeting, especially wall-to-wall "specials" of various kinds, often rely on quickly discounted notes obtained through deceptive sales tactics.<sup>38</sup> In addition carpet companies seem especially prone to mercurial tenure in the marketplace.<sup>39</sup> The record for this proceeding contains substantial evidence of reliance on cut off devices subsequent to deceptive carpet sales.<sup>40</sup>

**Alarm Systems.** As with "health spas," discussed above, sales of fire and burglar alarm systems appear to be an especially fertile field for consumer fraud and

abuse of the privileged status the law confers third party holders of promissory notes.<sup>41</sup> The record contains several case histories, one involving a number of individual consumers.<sup>42</sup> Dubious referral sales techniques and amounts of indebtedness which grossly exceed the actual value of the goods sold are common features of these cases.<sup>43</sup>

**Swimming pools.** Consumer frauds are most often associated with the poor and less advantaged of the community. Certainly this is correct to some extent,<sup>44</sup> but the same procedures used by the predatory inner city merchant can and do permit consumer fraud in certain commodity lines generally regarded as the province of the more well-to-do. Swimming pools are one such commodity. A swimming pool may cost no more than many of the home improvement projects mentioned earlier. However, swimming pools are a luxury item. For this reason, the fact that cases are related on the record is of interest.<sup>45</sup> It shows, together with other examples of expensive purchases, that more privileged consumers are victimized by similar practices and is further justification for across the board relief.

**Miscellaneous.** Holder in due course and other cut-off devices operated to foreclose consumer defenses in a wide variety of other consumer purchases. Among them: vacuum cleaners,<sup>46</sup> kitchen utensils,<sup>47</sup> encyclopedias,<sup>48</sup> cemetery plots,<sup>49</sup> clothing,<sup>50</sup> a hearing aid,<sup>51</sup> and an employment placement service.<sup>52</sup>

**Common elements in all the cases on the record.** In the cases on this record, operation of the holder in due course doctrine or other cutoff devices reflects a number of common elements: (1) the execution by the consumer of a promissory note or waiver of defenses and subsequent negotiation or assignment of the contract by the seller to a third party financier; (2) seller misconduct in the transaction between seller and consumer—that is, an infirmity in the original sale—or the development of a fault or defect following the sale; (3) failure of the seller to remedy the defect or otherwise deal with the complaint of the consumer, either through absolute unwillingness on the part of the seller or due to the seller's disappearance from the market; (4) interruption in payments by the consumer to the financier; and (5) assertion by the financier of its protected status in order to obtain payment on the obligation.

It should be noted that the last element—assertion by the financier of its protected status—need not occur in the context of a law suit. The protected position of the holder may be made known to the consumer in collection efforts prior to litigation. Thus the record contains numerous instances where consumers were told that the financier "has no interest" in the original transaction and because the financier is not connected with the seller, payments must be maintained.<sup>53</sup> Frequently such an approach is sufficient and the financier need not assert "holder in due course" status in the formal context of a court suit.<sup>54</sup>

All of the elements outlined above are contained in the many case histories summarized above. In addition, the record shows that in cases where holder in due course status was asserted in collection efforts, a promissory note had often been negotiated hastily,<sup>55</sup> frequently across state lines.<sup>56</sup> These factors suggest a deliberate effort to take unfair advantage of protections afforded by law to third party creditors.

Nearly every witness at the hearings,<sup>57</sup> and many written submissions,<sup>58</sup> emphasized the degree to which a creditor's unfettered right to payment in these cases contributes to discontent among consumers, particularly the poor and less advantaged consumer.<sup>59</sup>

Oftentimes we have found a client sending a letter to a finance company explaining defects in the merchandise that they have purchased and they explain the reason for not making payments.

The finance company totally ignores that and they say you will have to talk to the person who sold it to you, and that person has gone, and the corporation explains the warranty is invalid or some other b.s.—excuse me. I have felt their frustration and their quiet outrage that they can't talk to the person that they owe money to about the problems of the piece of merchandise that they have purchased.<sup>60</sup>

Witnesses pointed out that the consumer has no opportunity or ability to bargain and often has no alternative to dealing with certain merchants.<sup>61</sup> All proponents of the rule stressed that the proposed rule would help restore confidence in the law and in the legal system, including the courts.

Mrs. Knauer, the President's Special Assistant for Consumer Affairs observed:

What is involved here is the fundamental idea of fairness and equity, the individual consumer's belief that the "system" serves him fairly; and the right of the people to have their economic and governmental institutions work for their benefit and protection. The "holder-in-due-course" doctrine contributes materially to the affected consumer's feeling of helplessness—and the feeling that the "system" does not serve him fairly.

In effect, the consumer caught in the "holder-in-due-course" game feels he is batted back and forth like a tennis ball—never turning up on the winning side.<sup>62</sup>

(3) Affirmative suits by consumers are not an adequate remedy.

The Commission further finds that aggrieved consumers are often not in a position to take advantage of the legal system. Where seller misconduct in a credit sale transaction has given rise to consumer injury, the consumer is theoretically in a position to seek damages or other relief from the seller in court. This would be the case even where a creditor financing the sale has a valid "holder in due course" defense which will insulate his claim for repayment. However, in such cases the consumer must pay the creditor holding his note or contract whether or not he ultimately receives a judgment against the seller. The amount of a consumer's damages in such a case may be substantial in real terms, hundreds of dollars or more, but such damages are rarely enough to at-

See footnotes at end of chapter.



tract competent representation. The sheer costs of recourse to the legal system to vindicate a small claim, together with the days of work that must be missed in order to prosecute such a claim to judgment, render recourse to the legal system uneconomic. In addition, the worst sellers are likely to be the most volatile entities where market tenure is concerned. They prove difficult to locate and serve, and the marginal liquidity which characterizes their operations makes collection of a judgment difficult or impossible even if they are successfully served. Bankruptcy or insolvency becomes a final barrier to recovery.

The evidence supporting this finding is substantial.<sup>14</sup> For example, Judge Arthur Dunn of Chicago testified as follows:

It's [a] terribly cumbersome device, necessitates the expense of discovery, difficulty of service of summons or proper service, difficulty of a defendant becoming a plaintiff, but one of the most disappointing areas of this is the area of the result which might be reached and receiving or the taking by the consumer of a judgment which is, for all intents and purposes, unenforceable. [Because] a corporation, that is defunct or just unable—unsusceptible of being located.<sup>15</sup>

And Ronald Fritsch, of the Chicago Legal Aid Bureau:

Now, many people ask, "Well, why is a holder-in-due-course rule such a problem for a consumer? The consumer can always sue the seller or he can bring the seller in as a third-party defendant." . . . [B]ut this right of the consumer to file a suit against the seller or bring him in as a third-party defendant is clearly [illusory]. It is illusory because it forces him to become a plaintiff and the plaintiff has many, many problems. He's got to effect good service of summons on the defendant.

The plaintiff usually has the burden of proof in his case. The plaintiff must obtain the evidence for his case through costly discovery procedures; and, if the plaintiff is fortunate enough to have a judgment entered for him, he must go through lengthy and expensive post-judgment proceedings to discover, attach, and/or garnish the assets of the defendant.

I have represented defendants in quite a few cases such as this, either on behalf of a buyer or against a seller or a third-party action against a seller, and I have found that, by and large, the buyers in these cases are more solvent than the sellers.

The seller is either an individual proprietorship or, if the seller happened to have been a corporation, the corporation [is in existence] only a couple years, and by the time the buyer gets around to suing or bringing the seller in as a third-party defendant, the seller is gone. Either the corporation is defunct or, if it's not a corporation, if it's an individual seller, the individual seller is self-employed, he has no wages to attach.

The credit consumer also has a very difficult row to hoe when it comes to seeking legal representation. If he is eligible for a Legal Aid attorney from one of the legal aid organizations, that legal aid attorney usually has many, many more clients to represent than he can possibly represent to the full in court.

If he gets a private attorney, if he has to seek a private attorney to represent him, that private attorney usually doesn't have the resources to bring in a seller as a third-party defendant.<sup>16</sup>

See footnotes at end of chapter.

These problems are compounded where a consumer tries to defeat "holder in due course status" in defending a proceeding brought by the creditor to compel payment. To show that a creditor is not entitled to superior rights which render the debt independent of seller misconduct, the consumer must prove that the creditor had "knowledge" of the seller's misconduct and/or that the instrument relied on by the creditor was obtained in "bad faith". Periodically, a continuing close relationship between a seller and a creditor has enabled an aggrieved consumer to meet these tests.<sup>17</sup> But success depends on obtaining skilled counsel; and heavy expenses must be incurred to obtain the discovery and documentation needed to show concerted efforts on the part of the seller and creditor. There is also a significant likelihood, whenever a consumer undertakes to defend a creditor's suit for non-payment, that such efforts will fail. Major consumer finance companies continue to rely on operating procedures which may be asserted to contest any subsequent effort on a consumer's part to show "bad faith" or "knowledge". In this connection, warranties of delivery and satisfaction are customarily obtained by the finance company from merchants whose paper is purchased. Whether or not a finance company elects to pursue a merchant under such a warranty after a deal goes sour, the warranty may always be produced in court to persuade the trier of fact that the finance company could not possibly have had knowledge of seller misconduct in the underlying transaction.

A specific example of the problems confronted by consumers who are victimized by unfair or abusive sales practices and seek to assert seller misconduct as a defense to a creditor's suit for payment is provided by the following letter, submitted for the record by a private attorney. The sale in question involved a swimming pool to a Northern Virginia family.

The tragedy of this situation is that Mrs. Keatts and her husband are unable to provide themselves with counsel. . . . [A]s you know, in order to make a case based upon the Unico doctrine, considerable time would have to be expended in conducting discovery in the form of interrogatories, requests for admissions and possible depositions which might also include motions to be argued before the court concerning the copying of documents which, may be necessary to establish a link between the lender, the financier and the seller of the goods. Most attorneys, especially in a case of this kind where "new ground is being plowed" require a sizable deposit for costs, probably in the neighborhood of \$200.00. Additionally, the total attorney's fee in a matter such as this may be well over \$500.00. When faced with this set of realistic facts most clients who get into such a situation in the first place are unable to provide themselves with protection in the form of adequate counsel.<sup>18</sup>

Where waivers of defenses are permitted, the aggrieved consumer may have special problems. Inasmuch as the waiver relied on by the creditor is contained in the consumer's installment contract, the consumer may be said to

have had constructive, if not actual, notice of its presence and significance. This may be the case, even though consumers are seldom aware of the existence or meaning of such boilerplate, and even though the waiver appears in a form instrument which is certainly not the product of bargaining between the parties to the sale.

For these reasons a number of state courts have held that boilerplate waivers in installment contracts violate public policy.<sup>19</sup> Such clauses invoke the harsh consequences of negotiability by mere stipulation of the parties. Negotiability by stipulation or agreement was not countenanced by the Uniform Negotiable Instruments Law,<sup>20</sup> nor is it sanctioned by the Uniform Commercial Code.<sup>21</sup> Moreover, many states have banned the use of waivers outright or curtailed their use in consumer transactions.<sup>22</sup> It must also be noted that a waiver of defenses may arise in a manner legally identical to holder-in-due course status.<sup>23</sup> That is, the waiver of rights can arise by operation of law, without the knowledge of the consumer.

Support for the waiver ban in the proposed Rule was widespread.<sup>24</sup> Many witnesses emphasized that such agreements were really contracts of adhesion, designed to deprive the consumer of his right to raise defenses.<sup>25</sup> Whether a waiver arises by contract or by law, its effect is analogous to the use of a promissory note. In this connection the Uniform Commercial Code expressly analogizes waivers to "Holder in Due Course" status.<sup>26</sup>

<sup>14</sup> See Countryman, "The Holder in Due Course and Other Anachronisms in Consumer Credit," 52 *Texas L. Rev.* 1, 2-11 (1973).

<sup>15</sup> E.g., *Unico v. Owen*, 50 N.J. 101, 232 A.2d 405 (1967) (seller insolvent); *Norman v. World Wide Distrib., Inc.*, 202 Pa. Super. 53 195 A.2d 115 (1963) (seller disappeared).

<sup>16</sup> Countryman *supra*, note 1 pages 10-11.

<sup>17</sup> Kripke, "Consumer Credit Regulation: A Creditor-Oriented Viewpoint," 68 *Colum. L. Rev.* 445, 472 (1968).

<sup>18</sup> *Consumer Credit in the United States*, Report of the Natl. Commission on Consumer Finance (1972) page 36.

<sup>19</sup> Tr. 47-49.

<sup>20</sup> E.g., Robert Doyle, American Bankers Association, Tr. 1108; David Gezon, Volkswagen American Dealers Association, Tr. 1271; "There is no doubt that some limitations should be placed upon the applicability of the holder in due course doctrine and the enforceability of waiver of defenses clauses as they relate to certain consumer transactions." Michael Larson, Marine National Exchange Bank, R. 60; "I will readily concede that there are and have been abuses in the Seller-Holder-in-Due-Course relationship." R. E. Dean, President, Security Mutual Finance Corp., R. 95; "I have seen many abuses of the consumer by unscrupulous businessmen." Joseph L. Kaufman, Vice President, Pacemaker Corp. [boat manufacturer], R. 371; "There can be no question that there have been numerous abuses of the holder-in-due-course concept whereby retail sellers have, by immediately discounting their retail paper deprived a retail buyer of a practical means of asserting wholly valid defenses." Arthur B. Locke, Esq., on behalf of Connecticut Credit Union League, R. 166-1; see also R. 81, 83, 372, 1272, 1283, 1649, 1656, 1670, 1703, 1729, 1990, 2028. " . . . [T]he abuses are



a... very small percentage." H. W. Klockow, Vice President, First Wisconsin letter, R. 1701, 1704, 1705, 1706, 3383, 3384; "[T]his [proposed rule] is tantamount to amputating a leg because of an ingrown toenail." Stephen B. Friedman, General Counsel, Carte Blanche Corp., R. 3404.

<sup>18</sup> E.g., R. 62-63, 338-344, 581, 1297, 1590-92, 2487-95, 3428-31, 3587.

<sup>19</sup> E.g., Tr. 43, 109, 287, 422, 617, 874, 928, 1153, 1346.

<sup>20</sup> E.g., Sandon Members United To Act, Tr. 600-610; R. 1243-1258. Presentation by Robert Wagmen, Assistant Dean, St. Louis University Law School, on behalf of members of "Norm Sandon's Health Club." "This health club chain came to a quick demise in March [1971] when Internal Revenue seized the assets of the clubs for back taxes. At the time of the closing there were an estimated ten thousand or more [St. Louis area] families who had purchased membership in the clubs and as many as fifteen hundred who still were making payments on the notes." R. 1246. See individual cases at R. 2515 (Burns) and 2516 (Carrera), as well.

<sup>21</sup> E.g., Memphis and Shelby County Legal Services Association (100 cases), R. 1626-27; Legal Aid Society of St. Joseph County, South Bend, Ind., R. 1308-1310 (21 clients left with notes to pay when computer training school closed. "One day... the student arrived at the school to find that it had closed and that the building had been vacated during the previous night." R. 1308. "The... twenty-one students... represent only part of the class... [T]he ex-students will pay about \$3000 each for a training program which they did not receive." R. 1309).

<sup>22</sup> R. 2116-2141, see especially R. 2120.

<sup>23</sup> Legal Action Support Project, Analysis of the Response to the Questionnaire for Legal Services Projects (Leonard H. Goode, Project Director, Bureau of Social Science Research, Inc., Washington, D.C., September 14, 1971) R. 2117-2145.

<sup>24</sup> Id. at R. 2119-2120.

<sup>25</sup> Id. at R. 2120.

<sup>26</sup> "... [I]f all of the millions of poor with legal problems utilized legal services, it would be impossible to handle them." Fred Speaker, Director of Legal Services, Office of Economic Opportunity, Tr. 1026, R. 2112.

<sup>27</sup> Id. at Tr. 1027, R. 2112.

<sup>28</sup> E.g., Howard I. Kaufman, Chief, Consumer Fraud and Protection, Office of Attorney General, Illinois, Tr. 497; Virginia H. Knauer, Special Assistant to the President for Consumer Affairs, Tr. 894; Steven Mindell, Assistant Attorney General, Bureau of Consumer Frauds, State of New York, Tr. 9; Alan Sims, New Haven Legal Assistance, Tr. 212.

<sup>29</sup> Hon. Arthur Dunn, Tr. 757, 762, 765, 768. See also, e.g., Mindell, Assistant Attorney General, New York State, Chief of Bureau of Consumer Frauds, Tr. 23: "We don't keep statistical records, but [abuse of the holder in due course doctrine and waivers of defense] was the greatest single problem affecting the low income consumer." Fritsch, Tr. 756 (75% of Chicago Legal Aid cases involve HDC or W/D abuses); Groups, Tr. 886; Leatherberry, Tr. 1011; Myerson, Tr. 367.

<sup>30</sup> Memorandum Brief of the Wisconsin Department of Justice in support of the Proposed Trade Regulation Rule, R. 1756-1762.

<sup>31</sup> Richard F. Halliburton, Legal Aid and Defender Society of Greater Kansas City, Inc., R. 2009. See also, e.g., R. 20, Atlanta Legal Aid Society, R. 31, Omaha Legal Aid Society ("our files are full of hdc abuses"); R. 1497, Civil Rights-Civil Liberties Research Committee, Harvard Law School. "We are confronted almost daily with the harsh and inequitable effects of the holder in due course doctrine. Legal Aid Society of Metropolitan Denver R. 3446.

<sup>32</sup> E.g., R. 1218; 2515-16; 3437-40; 3491-95; Tr. 414-416; Patricia Ahearn (Figure-Tone Spa of Staten Island, N.Y.) Tr. 55-61, documentation at R. 919-944; Lynn Burgess (Chicago Health Clubs, Inc.), R. 2569-2589. See also Federal Trade Commission cases in same subject area, e.g., Dkt. C-1851, Holiday Health Spas, Inc.; C-2134, Plaza Club, Inc.—European Health Spa, Inc.

<sup>33</sup> Norm Sandon's Health Club, St. Louis, Tr. 47-51; Tr. 210-212; Tr. 474-475.

<sup>34</sup> R. 101; R. 2511-2512; Tr. 563.

<sup>35</sup> R. 102; Tr. 626-628.

<sup>36</sup> Tr. 556-557.

<sup>37</sup> Tr. 638-639.

<sup>38</sup> Dale Carnegie course, R. 112-123; medical receptionist training, Tr. 51-55; "sales academy," Tr. 617-619.

<sup>39</sup> Televisions: R. 2055-2056, 2197, 2380, 2381-2382, 3428-3431; Tr. 110-112, 219-221, 300-301, 942-945, 1351, 1353-1356, 1387-1388. See also R. 101 (Stereophonic Phonograph set); R. 378-380 (\$1,000 color television-stereo combination); R. 1712-1715 (hi-fi set, referral sales technique).

<sup>40</sup> R. 70-72; Tr. 287-290, Tr. 744-747.

<sup>41</sup> R. 2050-2052.

<sup>42</sup> Tr. 243-244; Tr. 376-378.

<sup>43</sup> Tr. 428-431.

<sup>44</sup> R. 73 (Piano); Tr. 110-112 ("quartz broilers, central vacuum cleaner systems"; referral sales plan; postal fraud conviction); Tr. 301-302 (refrigerator-freezer); Tr. 744-747 (Sofa covers).

<sup>45</sup> See Comment, "A Case Study of the Impact of Consumer Legislation: The Elimination of Negotiability and the Cooling Off Period," 78 Yale L.J. 618, 619-621; Note, "The Pennsylvania Home Improvement Finance Act," 10 Villanova L. Rev. 309 (1965); Symposium, "Consumer Protection," 64 Mich. L. Rev. 1197 (1966). See also Magnuson and Carper, *The Dark Side of the Marketplace* 3-9, 24-25, 31, 39, 46, 68-69, 79, 105, 112-117 (1968). See also Federal Trade Commission cases on the subject, e.g., Dkt. 882, Southern States Distributing Co.; C-2218, Four States Enterprises, Inc.; file 692 3051, Arien Realty and Development Corp., E.J. Korvette, Inc.

<sup>46</sup> R. 1542, "District Couple Wins Suit '1955 Home Fraud Case'," *Washington Evening Star*, March 4, 1971, § B, p. 4. Plaintiffs received a \$22,000 award but Atlas Financial Corporation, the Philadelphia holder of the note, successfully defended against judgment being entered against them as holders in due course. A "restitution fund" established by the principals of the defunct Monarch Construction Company contained a grant total of \$5,800 for restitution of all 700 inner-city families which the U.S. Attorney's Office states were victimized by Monarch. See Jean Carper, *Not With A Gun*, (1973).

<sup>47</sup> See, e.g., Federal Trade Commission cases: Dkt. C-1920, Midwestern Construction and Supply Co.; Dkt. C-2317, Brolan Manufacturing Co.; Dkt. 8875, Certified Building Products, Inc.

<sup>48</sup> Aluminum siding: R. 124, Louisiana\* ("over \$10,000"); R. 125, Louisiana\* ("over \$25,000" note, including siding "never completed," and debt consolidation); R. 125-126, Louisiana; R. 332, Kansas\*; R. 1362, Illinois (§ 162; "I have no redress against Mastercraft."); Tr. 204-208 and R. 670-674, New York (over \$2,900); Tr. 821-821 Illinois\* (over \$5,000); Tr. 856-857, Michigan.

<sup>49</sup> Other home improvements: R. 100 (Bridge City, Louisiana); Tr. 465-466, R. 382-384 and R. 582-584 (Toms River, N.J.; \$4,897 kitchen remodeling; shoddy workmanship, never completed); R. 566-568 Englewood, N.J.; heating system; R. 581-582 (West New York, N.J.); R. 904-908 (Elmont, New County, Georgia); R. 1684-1685 (Bayshore, N.Y., central air conditioning; over \$1,700); R. 2196 (Philadelphia, Pa., \$1,863 furnace\*); R.

2609-2622 (Ridgefield, N.J.); R. 3425-3426 (Modesto, California); Tr. 113 (N.Y. furnace repair/replacement scheme); Tr. 296-297 (New Jersey); Tr. 408-411 (Elmont, N.Y.) Tr. 639-640, 661-662 Tr. 874-882, R. 1340-1356 (Chicago, Illinois).

<sup>50</sup> Id. Referral technique indicated above by asterisk (\*).

<sup>51</sup> E.g., Magnuson and Carper, *supra* note 36, at 14, 17, 51. See also Federal Trade Commission cases, e.g., Dkt. C-2211, Cattlemen's Quality Meat, Inc.; Dkt. 8880, Seekonk Freezer Meats, Inc.

<sup>52</sup> Payment of well over \$1,000 for a freezer which could be purchased for \$250 at most stores is not unusual. See note 43 *infra*.

<sup>53</sup> Royal Foods of East Providence, Rhode Island: "Induced by advertisements... promising reduced prices and increased convenience and the use of a food freezer, accompanied by the give-away of a dinnerware set, people contracted for the offered monthly food service. The predominant consumer complaints... were that the food supplied by Royal was inadequate... that reference to 'use of a freezer meant, in fact, that the consumer was required to purchase the freezer. The freezers... were often sold... at unconscionable prices, frequently in the range of \$1,000." R. 953-955, documentation at R. 957-962. "Mr. Allen... realized that he had agreed to buy, rather than rent, a freezer for \$1,087... Mr. Allen went to see his union's lawyer and was told there was no way he could get out of the contract since it was sold to a finance company. The lawyer told him that if he stopped payments he would be sued, have his wages garnished, and probably be fired from his job." Case history submitted by New York City Department of Consumer Affairs, R. 1024-1026; see also R. 1517-1518; 2195; 2197; 3517; Tr. 236-237; Tr. 413-414; Tr. 498-499; Tr. 543-544.

<sup>54</sup> Note 46 *infra*. See also FTC cases, e.g., Dkt. C-2129, Town and Country Auto Sales, Inc.; Dkt. C-2195, Jordan Motor Company.

<sup>55</sup> E.g., Illinois, Massachusetts, Michigan, Oregon, Pennsylvania, Mississippi and Texas (waivers only). But note that some states specifically exclude automobile sales from statutes restricting the holder doctrine or similar creditor remedies; e.g., District of Columbia (related creditors provision), Illinois.

<sup>56</sup> *New Cars*: Kirkland, R. 92-93, 2529; Cochiaro, R. 569; Fuller, R. 2053-2054; Tr. 928-930; Heltzman, R. 2198; Block, R. 2314-2349.

<sup>57</sup> *Used Cars*: Luras, R. 375-377; Hatch, R. 2193, Tr. 1159-1162 (related creditor); Gant, R. 2383-2384, Tr. 1356-1359 (related creditor); Combs, R. 3433-3434; R. 3516-3517; Washington, Tr. 43-46 Oswin, Tr. 66-69; Schlossberg, Tr. 857.

<sup>58</sup> The Block case, related by Benny Kass, Commissioner, National Conference of Commissioners on Uniform State Laws, at R. 1199-1202, R. 2314-2349. See Block v. Ford Motor Credit Co., 286 A.2d 228 (D.C. 1972). See also "Moves Gain to Halt Some Credit Practices Assailed by Consumers," *Wall Street Journal*, June 7, 1971, p. 1, col. 1.

<sup>59</sup> Note, "Translating Sympathy for Deceived Consumers into Effective Programs for Protection," 114 U. Pa. L. Rev. 395, 398-403 (1966). See also FTC Dkt. 8846, Kustom Enterprises, Inc.

<sup>60</sup> See note 50 *infra*.

<sup>61</sup> E.g., "I have had no satisfactory results from G.E.... who financed the carpet. In fact, they feel that they have no responsibility to me whatever and so stated." Mrs. Sophia Bell, Washington, D.C. (carpet firm out of business), R. 62; Dominick Florenza, testimony at Tr. 461-464, statement at R. 894, documentation at R. 587-593; "Mrs. Collins received a payment book from Budget Finance requiring her to pay... \$1,202.68, more than half of her yearly income, for



three small rooms of carpeting. [After the carpet began to come up] . . . Mrs. Collins called Budget Finance to discover that the carpet company had gone out of business. She . . . was told that Budget was not responsible for any promises [to 'make repairs free of cost for 25 years'] made by the store. She would have to continue making payments, rug or no rug." Case history submitted by New York City Department of Consumer Affairs, R. 1026-1028; R. 2196; Tr. 112-113 ("Pyramid or chain referral plan . . . wall-to-wall carpeting at prices ranging from \$27 to \$30 per square yard . . . which could be purchased retail locally for approximately \$7 a square yard"; postal fraud conviction); Tr. 358 (referral sales).

"A particularly alarming case is related in Schrag, "On Her Majesty's Secret Service: Protecting the Consumer in New York City," 80 *Yale L.J.* 1529, 1553-1555. The case is that of Foolproof Protection, Inc., which sold \$4 million in burglar and fire alarm systems door-to-door, exclusively in ghetto areas of greater New York City.

"R. 2195-2196 (fire alarms; Consumers "Emma Jackson, Ada Brewington and others. Merchants: Protect-A-Life Corp., R&S Fire Security Co. Holders in due course; 1st Pennsylvania Bank; Beneficial Finance Corp., Mercantile Banking Corp." Referral scheme in some cases. Amounts of indebtedness ranged from \$862.20 to \$1,031.40; R. 3400 (fire alarm; referral technique); Tr. 83-85 (burglar alarm); Tr. 612-616 (fire alarm; \$556).

"The New York City Fire Department certified to the Department of Consumer Affairs that the retail value of the fire alarm systems being sold by Foolproof for \$750 was no more than \$75. Schrag, *supra* note 50.

"See generally, Katz, *The Law and the Low Income Consumer* 215-250, 330-339 (1968).

"R. 64-65 (Virginia); Arthur Roddey (Englishtown, N.J.), testimony at R. 100-109; statement and documentation at R. 909-918 but see Walter G. Bellaris, Vice President, Industrial Valley Bank and Trust Co., Jenkintown, Pa., R. 562-563; R. 2197 (Philadelphia, Pennsylvania; \$4,085).

"R. 101.

"R. 338-344.

"R. 982-983 (door-to-door); Tr. 416.

"R. 1618-1623.

"R. 1686.

"R. 2198-2199.

"R. 3516.

"R. 1153-1158.

"E.g., Kessler, Tr. 1063; Williams, Tr. 70-73; Huffman, Tr. 84; Douglas, Tr. 1543; Scholl, Tr. 1723; Bluestone, Tr. 1849; Ryan, Tr. 1981.

"Weiner, Tr. 1153; Roberts, Tr. 420; Crandal, Tr. 1906; Nelson, Tr. 2117; Tahnk, Tr. 2199; Lattner, Tr. 229; Williams, R. 395; see also R. 20, 544, 1647, 5973, 7395.

"[O]ut of sheer exhaustion . . . the lady put her name on the paper to the tune of \$1,000 [for pots and pans]. When she went to rescind the contract the following day, the [salesman] told her he forwarded the paper to a finance company and that it was impossible to rescind the contract." Edwin P. Palumbo, Rhode Island Consumers Council, R. 416; "The consumer signs a contract committing him to pay about twice the fair market value for the freezer . . . These installment contracts are immediately sold to a finance company, which refuses to honor buyers' defenses on the ground that the misrepresentations made by the salesman do not appear on the face of the contract . . ." Lucy McCabe, Attorney California Rural Legal Assistance, R. 3426; Furness, Tr. 33; Weiner, Tr. 1153.

"All the examples of our testimony—you will have a locally incorporated vendor and

a foreign loan company. In one case, the frozen foods corporation, I believe it was the reverse, a freight vendor and a Rhode Island incorporated [finance] company, but they are all interstate in one way or another." Roberts, Tr. 420. See also, e.g., Eisendrath, Tr. 831; John Keller, Office of Superintendent of Public Instruction, State of Illinois ("many" finance agencies are outside the state), Tr. 568; Sims, Tr. 214, 224. Specific cases, e.g., Fuller, Tr. 928 (D.C.—Maryland); Roddey, Tr. 100 (New Jersey—Pennsylvania); Scates, Tr. 938 (D.C.—Maryland).

"E.g., Eiberson, Tr. 275; Gregg, Tr. 1361; Kripke, Tr. 450; Mindell, Tr. 22; Pettus, Tr. 1352; Sims, Tr. 223; Williams, Tr. 62, 70.

"E.g., R. 9, 32, 111, 388, 869, 1286-87, 1486.

"E.g., Cain, Tr. 1164; Charney (on behalf of Rep. Bella Abzug), Tr. 458; Rice, Tr. 75; Speaker, Tr. 1030.

"Allan Sims, New Haven Legal Assistance Association, Tr. 223.

"E.g., Charney, Tr. 458; Judge Arthur Dunn, Tr. 758, 768; Fritsch, Tr. 749; Rice, Tr. 75.

"Virginia Knauer, Special Assistant to the President for Consumer Affairs, Tr. 896, 897-898.

"E.g., Furness, Tr. 37; Carpenter, Tr. 845; Matsen, Tr. 285; Mullins, Tr. 1192.

"Tr. 760.

"Tr. 735-738.

"E.g., Unico v. Owen, 50 N.J. 101, 232 A.2d 405 (1967); Rehurek v. Chrysler Credit Corp., 262 So. 2d 452 (Fla. 1972); Westfield Ind. Co. v. Fellers 74 N.J. Super 575 181 A.2d 809 (1962); Commercial Credit Company v. Childs, 199 Ark. 1073, 137 S.W. 2d 290 (1940).

"Patrick D. Molinari, Esq., R. 64.

"American National Bank v. A. G. Sommerville, 191 Cal. 364, 216 P. 376 (1923). See also Fairfield Credit Corp. v. Donnelly, 158 Conn. 543, 264 A. 2d 547 (1969); Quality Finance Co. v. Hurley, 337 Mass. 150, 148 N.E. 2d 385 (1958).

"Warren, "Comments on Vasquez v. Superior Court," 18 *U.C.L.A.L. Rev.* 1065, 1067 (1971).

"U.C.C. § 3-104, Comment 2.

"E.g., Colorado, Laws H. 1076 § 2-303; Delaware, Title 6, § 4311(a); Hawaii, Rev. Stats. § 476-18(d); Maine, Rev. Stats. Title II, §§ 3-302 5(c) and 5(d); Massachusetts Gen. Laws, ch. 255D, § 10(d); Minnesota, Laws, Ch. 276 § 2(a) and 3(a); New Mexico, Pers. Prop. Law, ch. 41, art. 10, §§ 403(3) (a), 413(10) (e).

"Under Section 9-206(1) of the U.C.C. . . . an agreement by a buyer or lessee that he will not assert against an assignee any claim or defense which he may have against the seller or lessor enforceable by an assignee . . . A buyer who as part of one transaction signs both a negotiable instrument and a security agreement makes such an agreement." (Emphasis added).

"E.g., Eovaldi, Tr. 796; Kessler, Tr. 1057; Mindell, Tr. 25; Preloznik, Tr. 543, R. 924, 1201.

"E.g., Martin-Trigona, Tr. 584; Newman, Tr. 997.

"C.F. U.C.C. 9-206(1).

#### CHAPTER IV. COMMISSION FINDINGS WITH RESPECT TO THE USE OF SALE RELATED LOANS IN CONSUMER TRANSACTIONS.

A concern that the intended effect of the original proposed rule might be circumvented by merchant-arranged "direct loans" proved to be a significant issue as the proceedings on the proposed rule developed. Many spokesmen addressed this subject in general terms and urged the Commission to broaden the

proposal by covering spurious "direct loans."

For the sake of simplicity, the practice—variously referred to as "vendor-related loans," "specious cash sales," "interlocking sales/loans" and, more colloquially, "dragging the body"—will be termed "vendor related loans" in this Statement. The practice arises when a merchant, desiring to circumvent restriction upon the holder in due course doctrine, arranges for a consumer purchase to be financed by a cooperating financing agency. The resultant financial transaction has the appearance of a direct cash loan, payment of which can be enforced by the loan company without reference to the underlying transaction. An example, related by a consumer witness at the 1971 Washington hearings, will illustrate:

John Hatch, a witness, testified as follows:

"Mr. Hatch: Mr. Chairman, my name is John Hatch. I went to buy a used car. They gave me all kinds of guarantees. This was my first car, so I was very much excited. Mr. Compact says, 'I have some boys to take care of you.'"

"He took me to the American Consumer Discount House . . . I went into one room and he went into another room. They had the papers set up for me.

"This car wasn't financed under the Pennsylvania Motor Vehicle Law. They tried to say after I got the car it was a personal loan.

"I received the car and they told me the car was guaranteed for 30 days; anything after 30 days I would have to pay half the cost.

"I like to not get the car off the lot. After that I complained so much that after three days after I received the car I went back to the finance company. They said, 'This is your baby. We didn't finance any car. We gave you a personal loan'.

"They made out the check to Mr. Compact and me. The only thing I did was to sign the check.

"I could not use the car. The finance company wouldn't make the dealer fix the car. The dealer refused to fix the car.

"My home and all of my possessions were up for a sheriff's sale.

"They repossessed the car. They sold it to me for \$1,512, and about a month later they sold the same car for \$300 because it wasn't in good shape."

The transcript<sup>2</sup> and record<sup>3</sup> contain additional consumer case histories involving related creditor sales in several jurisdictions and in connection with various consumer purchases. Automobile sales seem to predominate, perhaps because in several jurisdictions automobile sales have been the subject of legislation specifically restricting the use of promissory notes and waivers of defenses.<sup>4</sup>

Most notable, however, was the experience in New York State. For many years New York had a 10-day "notice" provision, generally regarded as ineffective by consumer representatives.<sup>5</sup> In 1971 the New York legislature enacted a more rigorous, direct restriction upon the availability of cut-offs to third party assignees of consumer paper.<sup>6</sup> Although the law was still, in the view of consumer interest spokesmen, far from compre-

See footnotes at end of chapter.



hensive," the enactment placed New York among the handful of states with relatively effective legislation on the subject.

A startling development at the New York hearings—held only four months after the effective date of the new law—was the speed and extent to which the vendor related loan abuse had been seized upon by merchants and financiers desirous of circumventing the new law. The record contains several case histories concerning New York consumers caught in a "specious cash sale," as the practice is termed in New York. Numerous witnesses familiar with the New York experience expressed alarm at the sudden prevalence of the practice and urged the Commission to broaden the proposed rule to meet the related creditor abuse.<sup>10</sup>

As a result of the comments received in the first set of hearings, the second published version of the rule included provisions making it applicable to vendor related loans. In the reopened proceeding, this section of the rule received widespread support on the record, both through individual consumers who testified about their own experiences,<sup>11</sup> and from consumer and industry witnesses who approved of such a provision and urged its adoption.<sup>12</sup> Legal aid and community legal services attorneys in particular stressed the need for such a provision based upon the extensive experience in states which had enacted restrictions upon the holder in due course doctrine but had not addressed related creditors.

The second published version of the rule specified a number of situations indicative of a cooperative arrangement between seller and creditor. The specified situations included the following:

(1) Relation between creditor and seller by blood or marriage.<sup>13</sup> This definition was supported by testimony on the record.<sup>14</sup>

(2) and (3) Relation due to the preparation of forms used in processing credit applications.<sup>15</sup> This definition was supported by both comment and testimony.<sup>16</sup>

(4) Common control or affiliation of creditor and seller. This provision was similar to a feature of the District of Columbia "related lenders" law<sup>17</sup> and is supported on the record.<sup>18</sup>

"If there is a close relationship . . . I think it puts into [the] Rule what the courts have long held the close relationship between the . . . retailer and the finance company.

"It is the Universal Acceptance Corporation against Russell case that speaks of item 4.

"The director of Universal Acceptance was also director of wig Fair. They sold their wigs before Christmas with six-month servicing, only to go out of business in February, whereupon the Universal director put on his other hat and sued on the negotiable instrument. I mean this is something that somehow the court said were two different people . . ."

(5) Joint venture. Recommendation of Professor Fairfax Leary.<sup>19</sup>

See footnotes at end of chapter.

(6) Payment of consideration by creditor to seller. A feature of the District of Columbia Consumer Credit Protection Act<sup>20</sup> and Arizona's related creditor statute.<sup>21</sup> Support for the provision was offered by legal services lawyers.<sup>22</sup>

(7) Guarantee of loan by seller. This section derived from a provision of the Maryland "related creditors" law.<sup>23</sup>

(8) Five or more loans. This provision was an adaptation of the Massachusetts statute, which deems a sufficient connection with the seller to exist where the lender has made two or more loans in a one-year period the proceeds of which were used in transactions with the same seller and the lender was recommended by the seller.<sup>24</sup> The National Consumer Act contains a similar provision which specifies twenty such referrals.<sup>25</sup> This approach was also urged upon the Commission by the office of the United States Attorney for the Southern District of New York.<sup>26</sup> Several legal services representatives stressed that in their work under state law a provision similar to subsection 8 would be particularly useful. They suggested that PTC enforcement experience would parallel their own practice and that this subsection would, therefore, be most necessary.<sup>27</sup>

"We feel that provision is one of the most important in that in many cases we find again that by using discovery processes, we are still unable to find any type of connection between the lender and the seller.

"Most often we have been able to find that the same lender and seller have engaged in the same transactions 10, 15 or 20 times; that we feel that Subsection 8 is important, that it is useful."

(9) Relation by knowledge of seller misconduct. This subsection was derived from the Wisconsin Consumer Act and was similar to provisions of an analogous Illinois statute.<sup>28</sup> The knowledge of adverse claims and defenses and absence of good faith are classic tests used to deny holder in due course status to the assignee of a note. The provision received support on the record.<sup>29</sup>

As a whole, the related creditor portion of the rule received widespread support in this proceeding.<sup>30</sup> Most opposition to this rule was directed to the entire rule; that is, there is relatively little opposition on the record directed specifically to a related creditor section. Whatever specific opposition was registered focused on the alleged overbreadth of the related creditor portion of the rule. Additionally, opponents argued that the several individual provisions in the definition portion of the rule were vague or overly broad.<sup>31</sup>

From the record, and particularly from comments elicited in response to the nine cases of concerted conduct between sellers and creditors which were explored on the record, the Commission concludes that vendor related loans should be covered by any Commission rule in this area. Sellers should not be permitted to evade the rule by diverting business from the discount window to the loan booth. Many of the largest acceptance or discount financiers in the country are equally active in the "small

loan" industry. The prearranged loan is an efficient method of sales finance, since the costs involved to creditor and seller are comparable to those borne in a discount transaction. The revised version of the rule which we now promulgate has been designed to eliminate the related creditor problem, by treating all credit sales the same way. The final revisions of this important section will be discussed below, in Chapter VII.

<sup>1</sup>E.g., Forham, Tr. 630; Nelson, Tr. 725; Eovaldi, Tr. 806; Leary, Tr. 968, 979-980; Kessler, Tr. 1059; Kass, Tr. 1027; Gregg, Tr. 1364. R. 47, 70, 904, 1294, 1369, 2377-2378.

<sup>2</sup>Tr. 1159-1161. See also R. 2198.

<sup>3</sup>E.g., Tr. 887-888 (Illinois; used cars); Tr. 1153-1156 (Pennsylvania; employment placement service; consumer referred to a specific official at cooperating loan company); Tr. 1356-1359 (Maryland; used car).

<sup>4</sup>E.g., R. 125-126 (Louisiana; aluminum siding); R. 904-908 (New York; home improvements); R. 1590-1592 (Michigan; camper); R. 1684-1685 (New York; air conditioner); R. 2383-2384 (Maryland; used car).

<sup>5</sup>"In other words, it is written up as if the consumer went to the bank first, made a loan, and then came to this automobile dealer to buy the car."

"... this practice is so widespread, I would say it occurs in one-third of all automobile financing transactions in Philadelphia." Scholl, Community Legal Services, Inc. Tr. 1172.

<sup>6</sup>Mindell, Tr. 10-28, R. 682; Flicker, R. 971; Huffman, Tr. 87-90.

<sup>7</sup>N.Y. Pers. Prop. Law § 401 et seq.

<sup>8</sup>E.g., Furness, Tr. 34; Elbertson, Tr. 276.

<sup>9</sup>E.g., Givens, Tr. 3-4 (aluminum awnings), 354 (clothing peddled door-to-door), 357 (furniture), 358 (rug, referral sales); Spence, Tr. 114-115.

<sup>10</sup>Mindell, Tr. 18-21; Furness, Tr. 37-38; Spence, Tr. 114-115; Seymour, Tr. 246; Hynes, Tr. 247-249; Elbertson, Tr. 403; Schnapp, Tr. 482.

<sup>11</sup>E.g., School, Tr. 1723; Jeffrey, Tr. 1805; Kaufman, Tr. 1987; Crandall, Tr. 1906; Betty Burton, Tr. 1988; Wenclawski, Tr. 2213-19.

<sup>12</sup>E.g., Knauer, Tr. 1403; Guttman, Tr. 1523; School, Tr. 1722; Schick, Tr. 1738; Jeffrey, Tr. 1804; Ryan, Tr. 1978; Eovaldi, Tr. 2183.

<sup>13</sup>E.g., N.Y. Pers. Prop. Laws § 254(a); Md. Rev. Stats. Art. 11, § 197A(b)(1), Art. 58A, § 24(b)(1).

<sup>14</sup>E.g., Patricia Hynes, Tr. 249; Fairfax Leary, R. 2086.

<sup>15</sup>E.g., N.Y. Pers. Prop. Law § 254 (b) and (c); Md. Rev. Stats. Art. 11, § 196A(b)(5); 28 D.C. Code 3809(a)(1).

<sup>16</sup>E.g., Hynes, Tr. 249; Douglas, Tr. 1543; Leary, R. 2087.

<sup>17</sup>28 D.C. Code 3809(a)(2).

<sup>18</sup>Hynes, Tr. 248; Prof. Egon Guttman, Tr. 1529; Leary, R. 2087.

<sup>19</sup>Guttman, Tr. 1529.

<sup>20</sup>Public Interest Research Group, currently University of Pennsylvania Law School, R. 2087.

<sup>21</sup>28 D.C. Code 3809(a)(3).

<sup>22</sup>ARIZ. Rev. Stat. Ann. § 44-145(b).

<sup>23</sup>David Scholl, Delaware County Legal Services, Tr. 1729-1730; Utah Legal Services, R. 4391; Kansas City Legal Aid and Defender Society, R. 4717.

<sup>24</sup>Md. Rev. Stats. Art. 11, § 196A(b)(4); Art. 58A, § 24(b)(4).

<sup>25</sup>Mass. Gen. Laws Ann. Ch. 255, § 12F.

<sup>26</sup>National Consumer Act § 2.407 (1970), R. 2689-2690.

<sup>27</sup>Tr. 248-249.

<sup>28</sup>E.g., Scholl, Tr. 1729, 1730-1731, Byrd, Tr. 1770.



<sup>22</sup> Jerry Byrd, United Planning Organization, Washington, D.C. Tr. 1770.

<sup>23</sup> Ill. Rev. Stats., 1969, Chap. 121 1/2, §§ 517, 576.

<sup>24</sup> E.g., Byrd, Tr. 1770.

<sup>25</sup> E.g., Prof. Egon Guttman, Tr. 1529; Blair Shick, National Consumer Law Center, Tr. 1738-39; Jerry Byrd, United Planning Organization, Tr. 1769-70; Mildred Jeffery, UAW, Tr. 1805; Stuart Bluestone, Consumer Federation of America, Tr. 1849; Agnes Ryan, Chicago Legal Aid Society, Tr. 1980; Helen Nelson, Tr. 2114-15; Prof. Thos. Eovaldi, Northwestern Univ. Law School, Chicago Council of Lawyers, Tr. 2186; Thos. Tahnk, Supervisor of Consumer Credit, Minnesota, Tr. 2202.

<sup>26</sup> E.g., Pray, Tr. 1641-42; Morris, Tr. 1701; Alabama Independent Auto Dealers, R. 5307; See also R. 3472, 4660, 5140.

#### CHAPTER V. COMMISSION FINDINGS WITH RESPECT TO THE USE OF WAIVERS OF DEFENSES IN CREDIT CARD CONTRACTS

Americans carry over 275 million credit cards of all types including 55 million bank-issued cards and 5 million travel and entertainment cards.<sup>1</sup> All are issued by means of a master contract which contains a waiver of defenses analogous to that used in installment sales. If a controversy arises over the underlying consumer purchase, the cardholder cannot withhold payment from the issuer.<sup>2</sup> The effect for the consumer is much the same as the financing arrangements discussed above. The method—the charge card procedure—is, of course, different.

In the initial proceeding on the proposed rule, the possibility of the use of credit cards as a method of avoiding the consequences of restrictions on other cut-off devices received considerable attention. Proponents of the rule maintained that credit cards should be included in any final rule on the subject of buyers' claims and defenses.<sup>3</sup>

Opponents felt that credit cards should be excluded, largely because the procedure involved in a credit card transaction differed from that in other credit sales.<sup>4</sup>

In the original proceeding few demonstrated cases of consumer injury were cited.<sup>5</sup> There was general agreement by consumer witnesses that the credit card issuer's ability to insulate itself from cardholder claims and defenses does not result in widespread abuse.<sup>6</sup> The thrust of consumer testimony was that credit cards must be covered in any final rule to meet potential abuses.<sup>7</sup> This position was premised on several assertions.

(1) Use of credit cards is rising and the potential for abuses analogous to holder in due course is great.

(2) Reasons similar to those advanced in the case against contractual waivers of defenses; that is, that such waivers are contracts of adhesion and against public policy.<sup>8</sup>

(3) That credit card issuers are similar to "related creditors" in that they are aware of the business practices of the merchant.<sup>9</sup>

(4) Such waivers are unfair in an absolute sense.<sup>10</sup>

See footnotes at end of chapter.

(5) The acceptance by merchants of credit cards, and the display of credit card seals or "logos," gives rise to an implied warranty by the credit card issuer as to the merchant's reliability.<sup>11</sup>

Adverse witnesses at the original proceeding based their opposition to inclusion of credit cards largely on the following grounds.

(1) The Commission lacks jurisdiction over bank-issued credit cards.<sup>12</sup>

(2) Credit card waivers are not abused.<sup>13</sup>

(3) A ban on waiver agreements in credit card contracts would (a) make it impossible for credit card issuers to operate<sup>14</sup> and (b) hamper development of modern automated electronic banking improvements.<sup>15</sup>

(4) The credit card issuer has no way to control the retail selling practices of the merchant.<sup>16</sup>

(5) Credit card transactions are inherently different, or unique.<sup>17</sup>

In a reopened proceeding, the Commission revised its rule to contain a provision which would prohibit sellers from accepting credit cards issued in return for a waiver of defenses effective against the issuer.<sup>18</sup> In publishing the proposal the Commission was aware of the fact that—at the time—three states had regulated the use of waiver of defenses clauses in credit card transactions.<sup>19</sup> The Commission believed that both consumers and industry should have an opportunity to comment on the subject, in the context of a specific proposal, and that the degree to which credit card waivers might be productive of consumer injury should be explored on the record.

In the reopened proceeding many of the same arguments, both pro and con, were heard with respect to restriction of credit card waivers. Opponents, in addition to renewing their previous objections, noted that the Commission proposed to regulate such waivers indirectly through a requirement on retail sellers.<sup>20</sup> Banking interests maintained that the Commission could not indirectly control the activities of credit card issuers.<sup>21</sup> Industry representatives and other witnesses further noted the unique aspects of credit card transactions and the manner in which they differ from the other three-party financing arrangements addressed in the rule.<sup>22</sup>

Industry representatives again stressed the degree to which their operations are leading to sophisticated electronic transfer mechanisms which will greatly relieve an over-burdened funds transfer system. Opponents of credit card regulation maintained that to place restrictions upon such a system in its early stages of development would hamper the perfection of a system intended to bring long-term benefits to the public.

Consumer representatives repeated their requests that restrictions on credit card waivers be included in the final rule to close a substantial loop-hole in the protections afforded by the rule.<sup>23</sup> A few witnesses testified as to actual cases of consumer injury,<sup>24</sup> and a number of case histories were placed in the written record.<sup>25</sup> The majority of these involve

billing errors or other practices unrelated to the existence of the credit card waiver.<sup>26</sup>

The Commission concludes that consumer injury from reliance on the standard form waiver in credit card contracts is infrequent, when viewed in the context of millions of transactions.<sup>27</sup> At the same time, the continuing relationship between the issuer of a credit card and the subscriber tends to render abusive reliance on the insulation conferred by the waiver counterproductive. If the issuer wishes to retain a subscriber's business, he must seek to insure customer satisfaction in most cases. Credit card issuers can and do undertake to intervene in consumer disputes with sellers.<sup>28</sup>

Mrs. Knauer, Special Assistant to the President for Consumer Affairs, summarized the relationship between issuers and users of credit cards thusly:

"The credit card company investigates both the card holder to whom it extends credit, and the retail credit company from which it buys the card holder's debt obligation.

"The expectations of the purchaser in an installment sale, therefore, can be quite different from those in a credit card transaction.

"The credit card holder, however, knows when he signed a credit card charge slip that his obligation to the retail store will be paid by the credit card company. Thus, the consumer, in a credit card situation, makes the credit assignment himself. He, in effect, directs the retail store to assign his note to the credit card company of his, the consumer's choice.

"Secondly, consumers in each of these transactions often have different economic advantages, as well.

"Installment sales financing is most often used by lower and middle income consumers, while credit card transactions are usually restricted to middle or upper income consumers, people who are presumably better equipped to defend their economic interest.

"Moreover, some credit cards, such as bank credit cards, have become a new medium of exchange for many Americans permitting them to purchase goods and services throughout this country and many foreign countries without the necessity of carrying large amounts of cash or establishing local credit. In this respect, credit cards may be used as a substitute for currency in what is considered by the card holder as essentially a cash purchase.

"Prohibiting waiver, of defenses could well compromise a considerable consumer benefit from bank cards, with their far-flung acceptability as a cash equivalent.

"Finally, there has been substantial evidence of abuse of the holder in due course doctrine in the area of installment sales. I am sure that is one statement we could all agree upon. But I am not aware of similar abuse in credit card transactions.

"To some extent, I believe that is the result of self-policing by credit card companies. Most of them carefully investigate the retailers with whom they deal, and do not hesitate to sever relations with them and with sellers who do not provide satisfactory merchandise or services. This is exactly the sort of voluntary business action that can often provide the best protection for consumers."<sup>29</sup>

In addition to the information discussed above which has suggested that waivers of defenses in credit card contracts are not abused to the same extent as the "holder in due course" doctrine, the Commission is cognizant of recent



legislative developments, at the federal level, which will alleviate any existing problems in this area. The recently enacted Fair Credit Billing Act invalidates waivers of defenses in credit card contracts where a card is used to make a purchase of more than 50 dollars within the state where the user resides or within 100 miles of the place where the card is issued.<sup>31</sup> The Commission has no reason to believe that this legislation will not afford adequate protection to consumers at the present time.

<sup>31</sup> Ross, "The Credit Card's Painful Coming-of-Age," *Fortune*, October, 1971, p. 108. Travel and entertainment cards ("T and E") are American Express, Diners Club and Carte Blanche. Nationally distributed bank cards are Master Charge (Interbank Card Association) and the BankAmericard (National BankAmericard, Inc.).

<sup>32</sup> The cards issued by retail stores—at 120 million, the largest category of charge cards outstanding—do not pose this potential difficulty since they are not three party cards. Likewise, the 90 million travel cards currently held do not involve waiver agreements.

<sup>33</sup> E.g., Kessler, Tr. 1066; Swankin, Tr. 1365; Willier, Tr. 1038.

<sup>34</sup> E.g., Daniel (BankAmericard), Tr. 1235, 1254-5; Doyle (American Bankers Association), Tr. 109, 1128; Morgan Interbank Card Association ("Master Charge"), Tr. 1229; Serafine (Charge Account Bankers Association), Tr. 1073.

<sup>35</sup> E.g., the "Richter Sewing Machine Case" cited by Bess Myerson, Tr. 376-377.

<sup>36</sup> E.g., Eovaldi, Tr. 792; Forham, Tr. 630; Leatherberry, Tr. 1018; Swankin, Tr. 1371.

<sup>37</sup> E.g., Flicker, Tr. 404; Kassa, Tr. 1209; Myerson, Tr. 368; Eisdendath, Tr. 382-3. See also R. 334, 891, 1369.

<sup>38</sup> Eovaldi, Tr. 792; Kass Tr. 1209; Leary, Tr. 986; Martin-Trigona, Tr. 583; Willier, Tr. 1046.

<sup>39</sup> Eovaldi, Tr. 796; Kessler, Tr. 1066; Leary, Tr. 981.

<sup>40</sup> E.g., Buxbaum, Tr. 1306; Furness, Tr. 36; Leatherberry, Tr. 1018; Myerson, Tr. 368; Willier, Tr. 1046-1049.

<sup>41</sup> E.g., Eovaldi, Tr. 807; Leary, Tr. 981.

<sup>42</sup> Kass, Tr. 1209; Martin-Trigona, Tr. 575, 583.

<sup>43</sup> E.g., Daniel, Tr. 1249, 1251, 1259; Serafine, Tr. 1074, R. 1737 et seq. (American Bankers Association [ABA]); R. 1767 et seq. (ABA, Interbank, National BankAmericard and two other bank card associations).

<sup>44</sup> E.g., Badders, Tr. 1334, 1339; Serafine, Tr. 1086.

<sup>45</sup> E.g., Daniel, Tr. 1237, 1242; Doyle, Tr. 1113, 1134; Serafine, Tr. 1089.

<sup>46</sup> E.g., R. 1737, 1767 R. 2476-2479 (Charge Card Association). "It is clear that bank charge cards will form the foundation for a nationwide electronic payment system. [Submission included newspaper clippings in substantiation of this point]. To now burden that evolving system . . . would have intolerable consequences." Charge Card Association, R. 2477.

<sup>47</sup> E.g., Daniel, Tr. 1238, 1245, 1258, 1264; Doyle, Tr. 110; Serafine, Tr. 1081. One banker, however, after making such an assertion, proceeded to relate precisely how a member bank encouraged a reform in the selling practices of a health spa. Morgan, Tr. 1221.

<sup>48</sup> E.g., Daniel, Tr. 1235, 1254; Doyle, Tr. 1109, 1128; Morgan, Tr. 1229; Serafine, Tr. 1073, 1077.

<sup>49</sup> 38 Fed. Reg. 892. Proposed sections relevant to credit card waivers were:

(f) Credit card issuer. Any person, partnership, corporation or association, includ-

ing a bank, which by agreement extends to a cardholder the right to use a credit card in connection with a consumer transaction.

(g) Cardholder. Any consumer who enters into an agreement with a credit card issuer extending to such consumer the right to use a credit card in connection with a consumer transaction.

In any consumer transaction it constitutes an unfair and deceptive act or practice for a seller to:

(d) Enter into any agreement, contract or other obligation for participation in a credit card plan with any credit card issuer who:

(1) Takes or receives from a cardholder any agreement, contract or other obligation, except one conforming to Section II(b) of this rule, which contains any provision whereby the cardholder agrees not to assert against the issuer claims or defenses arising out of consumer transactions arranged with the issuer's credit card, up to the full amount financed with the credit card in that transaction.

(2) Places any time limitation on the rights of a credit card holder to assert claims or defenses arising out of a consumer transaction which is shorter than the period in which payments are to be made for the sale or lease or the date of final delivery of the goods or the completion of the furnishing of the services, whichever is longest.

<sup>50</sup> Ariz. Rev. Stat. Ann. § 44-145(A) (Supp. 1971); Ch. 1019 § 4 [1971] Cal. Acts, 2152-55 (adding Cal. Civ. Code § 1747.90); Mass. Ann. Laws Ch. 225, § 12F (Supp. 1971).

<sup>51</sup> E.g., Michael J. Larson, Vice-President, Marine National Exchange Bank, Milwaukee, Wis., Tr. 2123; Ronald E. Brandel, representing Western States Bankcard Association, Tr. 1652; Joint Bankers Statement, R. 6392.

<sup>52</sup> E.g., Witnesses cited note 17, *supra* and Hinkley, Tr. 1783; North American National Bank, R. 5891.

<sup>53</sup> E.g., Witnesses cited note 18, *supra* and Mrs. Virginia Knauer, Special Assistant to the President for Consumer Affairs, Tr. 1395; Prof. John C. Weistart, Assoc. Professor of Law, Duke University, Tr. 1469.

<sup>54</sup> E.g., Professor Egon Guttman, American University Law School, Tr. 1509; Blair Shick, National Consumer Law Center, Tr. 1736; Stuart Bluestone, on behalf of Consumer Federation of America, Tr. 1844-48.

<sup>55</sup> Jeffery, Tr. 1809-10; Dale S. May, Tr. 1930; Samlany, Tr. 2105; E. Thos. Garman, Tr. 2207; Edie Rosenfeld, Tr. 2233.

<sup>56</sup> Chase, R. 5760; Norris, R. 5663; Sweet, R. 5592.

<sup>57</sup> See notes 25 and 26, *supra*.

<sup>58</sup> Estimated at over 300 million transactions per year. Ross, op. cit. *supra*, note 1.

<sup>59</sup> Tr. 1221; Tr. 1930; R. 7670.

<sup>60</sup> Tr. 1403-1405.

<sup>61</sup> Public Law 93-495, October 28, 1974.

#### CHAPTER VI. OPPOSITION TO THE RULE

A. Opposition to the abolition of the holder in due course doctrine. Much of the support for the proposed Trade Regulation Rule concerning Preservation of Consumers' Claims and Defenses has been discussed above in previous chapters. Other, more generalized expressions of support for the proposal are discussed below.<sup>1</sup> This chapter will evaluate the opposition to the rule which was elicited in the course of public proceedings thereon.

For the most part, opponents of the rule directed their comments and testimony to the proposal as a whole. They

See footnotes at end of chapter.

did not emphasize particular provisions of the rule or focus on individual components of the proposal. Comments with respect to the proposed provisions relating to waivers of defenses in credit card transactions were the major exception. Our credit card proposal elicited the largest volume of specific commentary in opposition.

**Effect on cost and availability of credit.** In the course of rulemaking proceedings, industry representatives maintained that a Trade Regulation rule which restricted the use of promissory notes and waivers of defenses in consumer transactions would cause an increase in the cost of credit<sup>2</sup> and/or a decrease in the availability of consumer credit.<sup>3</sup> A negative impact on the operations of retail merchants was also predicted. It was argued that financial institutions would become unduly restrictive about the sellers from whom they purchased consumer paper<sup>4</sup> and they might even stop purchasing consumer paper altogether.<sup>5</sup> On the basis of these arguments, some businessmen suggested that their retail operations would be severely curtailed and that some among their ranks would be driven out of business due to a lack of financing.

David Gezon, President of the Volkswagen American Dealers Association testified that California and Pennsylvania legislation removing holder in due course status for assignees of contracts taken in connection with an automobile sale had "worked as a disadvantage to [dealers in those states]."

"Particularly in the young cases, they [the dealers] feel the banks have become terribly what we call 'turn downsy.' The turn downs have increased since the advent of this.

"In California . . . it has cut down sources of financing."

Joseph L. Kaufman, Vice President of Pacemaker Corporation, a boat manufacturer and owner of a retail boat outlet in New York, wrote that the New York Statute which eliminates the holder in due course defenses "has resulted in a material decrease in the sales of our boats at the manufacturers' level, and also at the retail level in New York."

Mr. George Jones of the Alabama Independent Automobile Dealers Association submitted a survey of the Association's membership which indicated that the practical impact of the Alabama "Mini-Credit Code" was adverse to both the Association membership and to Alabama consumers.<sup>6</sup> The survey, in Mr. Jones' estimation, tended to show that (i) consumers find it harder to get credit, (ii) there are more frequent credit rejections by banks since enactment of the code and (iii) many of those being rejected are worthy of credit. Mr. Jones concludes, therefore, that such restrictions will deprive "thousands of basically honest and decent" consumers of access to credit.<sup>7</sup>

Many businessmen predicted that damage to their businesses would result from the increased reserve accounts and recourse agreements that banks would require when buying consumer paper from sellers.<sup>8</sup> They argued that financial insti-



tutions did not want the responsibility of policing sellers and that sellers would not bear the risks or survive with additional red tape. Other arguments against the rule included the claim that many consumers would stop paying without cause,<sup>11</sup> and that the rule would interfere with free competition.<sup>12</sup> In particular, it was argued that the rule would result in unwarranted hardship for honest small businessmen, who cannot survive without readily available financing.<sup>13</sup>

There was also particular concern expressed for the individual, especially the minority businessman, just beginning a business without a previously established reputation.<sup>14</sup> This problem was discussed by Professor Homer Kripke:

I must say in all candor that the result of such a rule may be to make it more difficult for dealers to get financing when they are just starting business and have no background or experience to demonstrate that they do and can perform satisfactorily and this is maybe particularly acute in the minority areas where we are making every effort to get started with small business, but here the problem is anyway a problem of subsidization of small business. . . .

That relatively narrow problem should not in my opinion be permitted to obstruct what is a very sound reform having much broader implications than the relatively narrow problem of aiding small business.<sup>15</sup>

Representatives of financial institutions made many of these same arguments. They contended that certain banks and finance companies would be forced to leave the consumer credit field; that those who remained would require larger reserve accounts and more stringent recourse agreements; and that these policies would mean increased costs for sellers which would be passed on to consumers. Financial institutions also asserted that they would have to switch to direct consumer loans. This, they argued, would work further hardship on sellers. Finally, in order to meet anticipated demands of consumers, financial institutions suggested that they would have to enter the repair business.

Eugene Hart, Vice President of a Wisconsin Bank, commented on his bank's experience under Wisconsin's administrative rule which eliminates the holder in due course doctrine in home improvement contracts.<sup>16</sup>

Our main bank, Marine National, had been buying \$400,000 a month home-improvement paper. That paper had dropped to \$50,000 a month and we are making the fifty in direct loans. Our outstanding home improvement paper seven years ago was \$7 million. It's now \$3 million.<sup>17</sup>

Mr. Hart felt that banks will have to require large reserves which will decrease working capital and "... many will be forced out of business."<sup>18</sup>

Later in his testimony Mr. Hart was asked to elaborate on why there was such a great decline in the amount of home improvement paper accepted. He responded,

I think there has been a drying up in the business . . . no one in the banking business wants any paper that generates problems.

See footnotes at end of chapter.

We look to the sellers, the dealers that give us good paper, and if we see any degree of problem, we just don't want them on our books. . . . The home improvement business used to be strictly a time-selling business but now those people that remain are pretty legitimate.<sup>19</sup>

*Creditor obligation to police the market.* Industry members also asserted that they are in no position to know the status and reputation of retail merchants; that they cannot, realistically, be expected to police retail sellers.<sup>20</sup> This assertion is invalidated by other industry testimony which confirms that the volume of consumer sales-finance transactions is such that creditors have a full opportunity to detect and predict the incidence of consumer sales abuse on a statistically reliable scale.<sup>21</sup>

Additionally, this record reflects the fact that financial institutions have access to a variety of information which yields an accurate and reliable picture of a merchant's reputation. Creditors who finance consumer transactions can and do conduct thorough background investigations of any merchant negotiating consumer paper. This is true despite the fact that where a creditor occupies the protected status of a "holder in due course", he may look to the consumer debtor for payment notwithstanding seller misconduct.

In this connection, the record contains references to a variety of industry tools. For example, all lenders approved by the Federal Housing Administration to grant home-improvement loans automatically receive a list of individuals and firms which have failed to perform satisfactorily on FHA-insured home-improvement jobs. The list, maintained by HUD-FHA, is called the "Precautionary Measures List".

The list, which is kept up to date (names are continually added, and deleted if the contractor reforms), has at present [approximately 5000] names of companies [and individuals] for which the FHA refuses to insure loans, on the theory that it has a responsibility to the public not to be a party to deceit. Thus, every lender handing out FHA-insured home-improvement loans knows which home-improvement companies have acted in an unreliable manner and has guideline for its judgments in this area.<sup>22</sup>

Many finance industry witnesses indicated that their companies always screen the paper they purchase.<sup>23</sup>

We look to the sellers, the dealers that give us good paper; and, if we see any degree of problems, we just don't want them on our books.<sup>24</sup>

With reference to the Wisconsin Consumer Act, Mr. Bill W. Dixon, Vice President of the Wisconsin Installment Bankers Association, responded to the question, "has the Wisconsin law changed your operation in any way?" as follows:

Not significantly. There are some changes. Quite frankly we always investigated the merchants with whom we do business. We do a little better job now in the area of our credit approval.

There's not been any significant changes at this time, but we are taking a closer look at

certain types, I'd say, of marginal credit as a result of the new Act. . . .<sup>25</sup>

Richard P. McManus, Assistant Director, Law Department, Household Finance Corporation, testified,

Other steps we feel [are important] in protecting the consumer are trying to investigate the merchant from whom we purchase contracts.

This is probably a singularly most important aspect. In doing this, we make every effort to be sure that people from whom we buy contracts are ethical, responsible businessmen.

We buy paper only from those that we have personally investigated and our personal investigation goes into such matters as ethics, financial ability, financial capacity, business ability, so forth.

We categorically reject any merchant that has had substantial and substantiated consumer complaints registered with the Better Business Bureau.

It has been our experience that the best time to resolve complaints is early in the game. After that we maintain complaint records on each merchant with whom we deal and when we find that a merchant has a number of complaints that go unresolved, where there's been misrepresentation, so forth, we terminate our dealing with this merchant.

We think this program of merchant investigation and inspection is effective.

Once we establish an agreement with a merchant about paper, we conclude a financing agreement. United this arrangement we require him to repurchase any contract that relates to merchandise that has been unsatisfactory and not properly resolved.<sup>26</sup>

*Alternatives available to creditors.* Mr. McManus' final point adverts to a variety of contractual arrangements between creditors and retailers which operate to protect the financial institution in consumer transactions. One such arrangement is a "repurchase" or "recourse" provision in a contract between a retailer and a finance company. Such provisions obligate the retailer to assume full or partial liability for a consumer default on a related credit obligation. While it may be true that even the most conscientious program of screening sellers will not eliminate all risk of seller misconduct, a repurchase agreement of the use of a "reserve" account can protect the financial institution against any risk that remains. In this connection, the Uniform Commercial Code provides:

any person who transfers an instrument and receives consideration warrants to his transferee . . . that . . . no defense of any party is good against him.<sup>27</sup>

The code thus expressly recognizes and mandates imposition of the assurances Mr. McManus' firm routinely obtains from sellers.

Professor Homer Kripke testified about the use of various recourse arrangements in consumer transactions. His testimony is based on his experiences as counsel for large finance companies.<sup>28</sup>

Banks and financial companies have frequently urged that freedom from merchandise-related defense is essential for a financial institution, in order that it can service the merchants by acquiring from them the obligations of their customers. In so far as



these arguments rest on purported legal grounds, they seem to be without substance.

Thus, it is publicly argued by a finance company that if consumer installment obligations acquired by it from sellers were subject to consumer defenses, the obligations could not be carried on its balance sheet as assets and this disadvantage would make it impossible for the company to engage in the financing of consumer obligations for dealers. The same company, however, is heavily engaged in factoring, which likewise consists of holding obligations of buyers purchased from sellers (usually in a commercial context). No effort is made in the factoring business to protect the third party from defenses between the original parties by a waiver of defense clause or use of negotiable note, and yet the factoring receivables always appear on the balance sheet of the financing institutions handling them.

Similarly, the banks have sometimes publicly argued that if consumer installment obligations purchased from merchants were subject to defenses, they would not be legal for investment by banks, because they would not be firm obligations. This is specious reasoning, in my opinion. Banks have always discounted negotiable notes arising in merchandise transactions, and have relied on the holder in due course doctrine. That doctrine does not give protection against the "real" defenses of the maker, namely fraud in the factum, infancy, incapacity, duress, illegality including usury, etc. See Uniform Commercial Code Section 3-305 which is in force in nearly every state. This means, therefore, that whenever a bank discounts a note which had its inception between a buyer and a seller, the bank is subject to all the possibilities of holding an unenforceable note arising from usury, fraud in the factum, infancy, etc. Thus, there may be complete legal defenses to the obligation held by the bank, and the proposition asserted that banks may not hold obligations which may be unenforceable would preclude the bank from ever holding notes created by other parties. It obviously is not the law.

Thus the question of additional customer defenses arising from merchandise misrepresentations or breaches of warranty does not involve a basic change in the legal position of the banks, but merely a substantive change in the possible extent of the risks of uncollectibility which they provide for by their reserves for losses.

This brings us to the second and perhaps more significant aspect of the claims of the financial institutions, namely, that they cannot afford to handle consumer installment obligations if they are subject to the risks of customer dissatisfaction. I considered this question for many years when I was counsel for a large consumer finance organization and in subsequent years of practice specializing in that field. In 1950 I took the position in the Yale Law Journal that although the holder in due course doctrine was properly applicable in this situation, the question was really of little practical moment—it was much ado about nothing. *Kripke, Chattel Paper as a Negotiable Specialty*, 59 Yale L. J. 1209, 1214-1222 (1950). I was then speaking in the context of the business of a company which prided itself on its reputation and the character of the business it was doing, and would have been quick to refuse to do business with dealers who produced a significant amount of customer dissatisfaction. Subsequently, when the New York statutes [restricting the holder-in-due-course doctrine] were passed, the question arose in that financial organization whether we should insert in our contracts the clause authorized by statute that would invoke the waiver of de-

fense argument. The Vice President then in charge of operations decided, with my advice and concurrence, that the nature of our operations was such that we would not need the protection. That company had long since voluntarily abandoned the negotiable note as a means of obtaining that kind of protection.

I cannot believe that banks do or should do a lesser quality of business than this or are in any greater need for protection from the customers of banking clients. It would be interesting to see whether any bank would so denigrate the quality of its own operations as to submit figures showing that this issue is important in its collections. I have a hunch that the issue will prove to be statistically meaningless for the banks, and rests more on a yearning for clear lawyers' opinions about enforceability than on facts. A bank ought to do no less than a factoring company, namely, to investigate its client's experience with customer claims for adjustment and returns, and to refuse to do business with a merchant whose percentage thereof is too great.

It may be useful to clarify a point here. Some endorsements of negotiable notes by merchants for the sale of customer obligations to banks are "without recourse". Likewise, in the factoring business, which involves the sale of non-customers' obligations to the factor is done "without recourse". These terms do not mean that as between the financing institution and the merchant, the financing institution assumes the risk of customer dissatisfaction. The underlying agreements always contain a warranty by the merchant to the institution that the customer has received and has accepted the goods and has no claim with respect thereto; therefore if the customer does have a claim that a warranty has been breached, the financing institution does have recourse against the merchant. This problem, therefore, can arise as ultimately significant only in cases where the merchant has become insolvent and the question is whether the customer or the financing institution must take the loss. Even with an insolvent merchant the financing institution frequently need not take the losses, because many financing arrangements involve the withholding from the merchant, exactly for this purpose, of a portion of the purchase price paid by the financing institution to the merchant for the customer obligation. In any event, the bank is in a far better position than the customer to determine whether a merchant is insolvent and is likely to be in a position where he cannot honor his warranties and representations as to the merchandise sold.

This problem has become acute as the installment credit system has moved from reputable merchants and financing institutions serving middle-class customers into the poverty areas where needy and ignorant customers are preyed on by disreputable merchants. In this context my assertion of 1950 that the problem is unimportant factually no longer holds true.

The question is whether banks and other financial institutions are going to make available an immunity in a third-party position to support business operations which inflict severe monetary damage and other distress on ignorant weak people by disreputable means. The only effective means of control of these merchants is by making it the interest of the financing institutions to deal only with reputable merchants. This can be done only by abolishing the financing institutions' opportunity to get free of merchandise defenses. The banks ought to be ashamed of arguing that they are serving merchants whose injuries to their customers are so substantial as to constitute a significant impairment of the collectibility of the obligations.

*Commission resolution of cost and supply questions.* As noted earlier in this chapter, one of the major points in opposition to the rule concerned anticipated adverse effects on the cost of supply of consumer credit. In considering this issue, the Commission has carefully reviewed the material in the public record, especially the testimony of law enforcement officials and other witnesses from those jurisdictions which have enacted or adopted effective statutory restrictions upon the holder in due course doctrine and other cutoff devices.<sup>24</sup> Additionally, the Commission has reviewed the comprehensive work of the National Commission on Consumer Finance on this specific issue<sup>25</sup> and has noted the testimony of representatives of the NCCF staff on the record for this proceeding.<sup>26</sup>

When the initial proposal in this proceeding was published, relatively little "hard evidence" or economic data was available concerning the demonstrated impact of legislative efforts aimed at restriction of the holder doctrine and other cutoff devices. The only evidence available at the time was ambiguous data drawn from the State of Connecticut.<sup>27</sup>

In the course of this proceeding the Commission has received considerable testimony concerning the impact of emerging state legislation similar to the rule. Almost without exception it supports the finding that there has been little, if any, negative impact from such legislation.<sup>28</sup> This conclusion was advanced by industry witnesses and was implicit in their assessment of the impact of laws in states with which they were familiar.<sup>29</sup> For example:

It is fair to say then—let's narrow it to your experience in California . . . —that by and large the holder in due course doctrine is a dead letter, and that as a matter of fact financial institutions are still flourishing?  
Mr. Smith: They are flourishing . . .

The bank financing of automobiles is expanding.

I don't think the Rees-Levering [Act] change has persuaded any banks to get out of the automobile financing business.<sup>30</sup>

Consumer witnesses made similar assertions. Blair Shick, Legislative Coordinator of the National Consumer Law Center, Boston, testified as to the Massachusetts experience.

In Massachusetts, for example, it was the first state to abolish holder-in-due-course in a comprehensive sense through consumer transactions. There is absolutely nothing to indicate that as you compare Massachusetts with, say, Connecticut, a very analogous state, that anything has changed, that there was a need to change the rate structure, that people in Connecticut that are low income people are getting credit that aren't in Massachusetts. There was just no evidence of that.

The Massachusetts banks have a—almost a decade of experience. They don't come forward with their internal data. We can only look at the external and say it doesn't happen, it's never happened, that restricting one of these remedies or applying it here against a holder in due course has made any meaningful difference at all in availability of credit or the price of credit.<sup>31</sup>

See footnotes at end of chapter.



Finally, these facts were also confirmed by State law enforcement officials based on their experiences.

Richard Victor, Assistant Attorney General, Wisconsin Department of Justice, said:

We are very fortunate in Wisconsin in that the problem which is dealt with by your proposed rule has been covered in depth by the Wisconsin Consumer Act.

The Wisconsin Consumer Act prohibits negotiable instruments in consumer credit sales transactions as well as interlocking loan.

These interlocking loans are substantially the same by definition as your related provisions.

The Act also provides that waiver of defense clauses are ineffective for the first 12 months following assignment.

It is clear that in the Wisconsin Consumer Act and yours as well fills an urgent need without unduly burdening the business-man.<sup>28</sup>

A nationwide survey conducted by the National Commission on Consumer Finance provides the most authoritative evaluation and prediction of expected impact of this rule. It supports the assertion that this rule will not unduly burden business or consumers. Douglas F. Greer, Professor of Economics at the University of Maryland, and formerly Economic Consultant to N.C.C.F., discussed his work in this area during hearings on the rule.

The second major part of my testimony relates to our attempt to . . . determine the extent to which credit availability would be reduced or interest rates affected by abolishment of these two remedies.

\* \* \* what we do with the econometrics \* \* \* is to attempt to isolate the effect of one variable by holding the influence of all relevant variables constant, and in that way we can estimate the impact of one variable, a dependent variable, such as extensions of credit or interest rates.

And this is basically the way we attempted to treat the matter here.

\* \* \* the observations in terms of denial of these remedies was in terms of those states that have prohibited both waiver and holder \* \* \*

\* \* \* it can be concluded that denial of these remedies is likely to reduce credit availability of one particular type . . . That is: installment credit written at the retailer \* \* \*

Professor Greer predicted a reduction in the amount of credit extended in connection with certain consumer sales transactions in the neighborhood of 5 to 10 percent.<sup>29</sup> This suggests a very slight impact is likely from restrictions on cutoff devices in consumer sales. A finding that this rule may marginally reduce the aggregate amount of sales-related credit which is extended is not a persuasive argument against its adoption.<sup>30</sup>

Elimination of cutoff devices in consumer transactions should have the effect of causing creditors to be reluctant to finance transactions with merchants who engage in disreputable or unethical sales practices. Predatory merchants will thus find it more difficult to obtain a line of credit. At present, sellers are in a position to unload paper rapidly to willing acceptance creditors, leaving the creditor

to worry about collection. The creditor, in turn, need not concern himself about abusive sales practices. He may rely on his statutory or contractual insulation from the seller in the event that a dispute arises in the process of collection.

An excellent example of such conditions and their adverse impact is afforded by the Monarch Construction case in the District of Columbia. Monarch Construction promised home improvements to owners of rowhouses in lower-middle income and lower income areas of the city. In return they took promissory notes which represented staggering consumer indebtedness—often many times the annual income of the maker. The promised home improvements were usually never undertaken; if begun, they were not completed. Had the promised work been done, its acknowledged value would have been far less than the indebtedness incurred.

Had this rule or a similar state statute been in effect, Monarch Construction Company would have been an obvious "reduction" in the amount of aggregate consumer credit outstanding in the District of Columbia. However, this reduction would not necessarily have included all of the potential demand for home improvement work that was ultimately absorbed by Monarch. It is reasonable to expect that those of Monarch's customers who really needed home improvement work, and reached this conclusion without the help of the high-pressure sales tactics which characterized the Monarch operation,<sup>31</sup> could and would have sought financing for legitimate contracts executed with reputable firms. The evidence that a reputable firm would have charged far less than Monarch, for vastly more comprehensive work. It should be clear that the reduction in outstanding credit occasioned by the application of the proposed rule to a Monarch-like seller reflects both social utility and an improvement in the financial situation of individual consumers.

Let's suppose that abolition of the rule dries up the credit to the "food-freezer-racket" operator. This is the fellow who unloads freezers having a retail value of not more than \$300 at a price of \$900 to which he adds interest, insurance, and other charges. I think we should ask "Who needs that kind of credit?" We should ask the same question if we should find that the rule dries up credit to the seller of shoddily made sewing machines at outrageously high prices. We can also do without the credit that enables the home improvement swindler to move with the good weather up and down the East Coast.<sup>32</sup>

During these proceedings proponents from many of the jurisdictions which have enacted legislation similar to the rule indicated that no significant increases in cost or decreases in availability had been observed. They also pointed out that consumers in all economic classes have been harmed by application of the cutoff devices the rule will prohibit. We believe that the benefits to consumers occasioned by this rule vastly outweigh predicted impact on credit or supply.

Readily available credit from a fly-by-night salesman who does not deliver the goods or perform as promised does not benefit consumers. The record contains hundreds of examples of this type of transaction. We agree with the many proponents of the rule who stated that honest merchants, financial institutions and consumers alike will benefit by state and federal regulation which restricts the operation of predatory sellers.

The record of this proceeding shows that the inequities of the present system will be eliminated if a greater responsibility is placed upon the financial institutions to police the merchants with whom they deal. The costs associated with this rule will be shared by banks, other financial institutions, sellers, and ultimately consumers. Witnesses in support of the rule frequently likened increased costs to "insurance premiums" paid to obtain a general improvement in retail sales practices.

The industry argument that credit should be made available to marginal risks by retention of cutoff devices was uniformly rejected by proponents of the rule. If methods to extend availability of credit need to be found, they should be undertaken as an affirmative effort to develop innovative new programs, such as establishing incentives for reputable "general market" retailers to extend credit to the working poor or to open branches in low-income neighborhoods so that the poor might have access to quality goods at competitive prices. The solution to the problem does not lie in continuing a credit practice which has been shown to be injurious to all consumers.

Finally, the record reflects little likelihood of any significant impact on interest rates. This fact is confirmed by witnesses from reform states. It is also confirmed by the work of Dr. Greer and the NCCF, as Dr. Greer testified:

The second major part of my testimony relates to our attempt to . . . determine the extent to which credit availability would be reduced or interest rates affected by abolishment of these two remedies \* \* \*

Finally, we attempted to estimate the effect of denial for the interest rate on such credit; that is, credit extended at the retailer's and we find that the interest rate is reduced slightly as a result of abolishment of these remedies, the interest rate charged to the consumer and also the net interest rate earned by financial institutions buying this credit paper.

The retailer's participation does not seem to be affected; it is only the net rate earned by the financial institution and the consumer rate.

Now, I think that this result is due to the fact that with abolishment of these provisions there is a change in the quality of the credit and also the risk burden borne by the financial institution, such that with the lower risk burden borne by the financial institution the rates of charge are going to be lower.<sup>33</sup>

We conclude this discussion with reference to the testimony of Thomas Tahnk, Supervisor of Consumer Credit for the Minnesota Department of Commerce. It summarizes many of the concerns raised in the course of proceedings on this rule.

See footnotes at end of chapter.



Information for this statement was gathered from a cross section of all licensed financial institutions and from consumer protection groups both in and outside of government.

The State of Minnesota enacted a law in 1971 similar to the proposed trade rule dealing with intra-state transactions.

To the extent that our two years of experience under the Act might provide some indication of its probable impact on the nation as a whole we would like to summarize the Act, its impact on our economy and its shortcomings.

We feel that the proposed trade rule will address itself on a national level to basically the same problems that our law deals with on the local level. We view the proposed trade rule as a companion to rather than a substitute for our law.

The real impact seems to have been on the smaller finance companies serving the lower middle class and poor areas. Such residents were unable to obtain bank financing—not because it wasn't desirable—they just didn't qualify. So they financed their purchases from car jockeys, bait and switch sewing machine companies and secondhand appliance dealers through local finance companies. Transactions were handled on both conditional sales contracts and loans through related creditors. These companies did employ the holder in due course doctrine on a regular basis.

The Legal Aid Society and Better Business Bureau report that the new law has been very effective in persuading used car dealers that a \$900 used car should have more than a five minute warranty; in convincing used furniture dealers that a sofa sits better with four legs; and that the stereo really isn't "free" when one has to purchase 50 record albums at \$7.95 a piece. Reputable finance companies, out of economic necessity, were forced to carefully select their dealers.

Has the law hurt business?

Is it harder for the poor to obtain sufficient credit?

We don't think so.

Finance companies are out daily beating the pavement searching for good dealers; they find that there's never enough.

Legal Aid attorneys attempting to unweave the financial messes of their clients report that there is more than adequate credit available.

We conclude that the new law has helped those it was intended to help and has not, as was first feared, acted as a damper on the economy.

Minnesotans have lived under the Act for almost two years. From our vantage point, we feel that the Act has been good for the state, both its consumers and its businesses. None of the dampening effects on our economy that were feared have occurred.

We in Minnesota support the adoption of the proposed trade rule.<sup>17</sup>

B. Opposition based on related developments in the field. In the original proceeding, many parties urged that the Commission withhold action until the report of the National Commission on Consumer Finance was completed and published.<sup>18</sup> That report was released in January, 1973.<sup>19</sup> Among the recommendations are proposals to abolish the holder in due course doctrine and waivers of defenses, and to sharply restrict vendor-related loans.<sup>20</sup>

In the reopened proceeding, the Commission was urged to wait at least four

years from the date of the NCCF report, in order that the individual states might have an opportunity to enact the NCCF recommendations.<sup>21</sup> Additionally, it was pointed out that the recommendations of the NCCF were intended to be considered as a comprehensive proposal which ought not to be acted upon piecemeal.<sup>22</sup>

The Commission does not agree that the restrictions embodied in this rule cannot be enacted as an independent regulation, separate and apart from the comprehensive, large-scale changes recommended by the NCCF. Many states have legislated restrictions similar to this rule without undertaking concurrent changes in the interest rate ceiling or other aspects of consumer finance. In addition, the Commission notes that NCCF statistics strongly suggest that alteration of rate ceilings is not necessary when considering a restriction of third party cutoff devices.<sup>23</sup>

The Commission has therefore determined that further delay in restriction of devices which serve to cut off consumers' defenses against third party financiers is not warranted.

**State action:** Many states have acted in some manner to alter or eliminate the traditional holder in due course and waiver of defense doctrines as applied to consumer installment sales. The question thus arises whether state action has made Commission action unnecessary. In general, industry representatives said yes<sup>24</sup> and consumer representatives said no.<sup>25</sup> After careful review of the statements in the record and existing state legislation the following observations can be made.

(a) Of all the states that have legislated, only a few have enacted a comprehensive measure.<sup>26</sup> Some states have abolished either the holder in due course doctrine or waiver of defense clauses, but not both.<sup>27</sup> Many states have not dealt with the problem of the vendor-related loan.<sup>28</sup> In other states, major exceptions or exclusions are contained in the legislation, or the statute applies to only one type of transaction, e.g., automobile sales, home solicitation sales, home improvement sales, to the exclusion of others.<sup>29</sup> These partial limitations do not reach the full extent of the problem.<sup>30</sup> (b) Consumer representatives noted on the record, that in states that have not acted, the opponents of consumer credit reform are so strong that no statute is likely to pass.<sup>31</sup>

(c) The considerable number of interstate consumer credit transactions which may elude even the most comprehensive state statutory protection<sup>32</sup> will be affected by this Rule.

(d) Proponents of the rule emphasized a need for uniformity of protection. They believe that a comprehensive trade regulation rule, uninfluenced by local pressure, would be a major step in achieving this goal.<sup>33</sup>

(e) While a growing number of state courts have held application of holder in due course or waiver of defenses to be unconscionable when applied in consumer transaction,<sup>34</sup> such decisions are not comprehensive in effect. Judicial re-

lief requires more time and money than most consumers can afford and it is only available in the most extreme cases.<sup>35</sup>

For these reasons the Commission concludes that this Rule will serve as a model for further state legislation and give states which lack legislation impetus to act.<sup>36</sup> The argument that the Commission must always "wait for others to act" is not a persuasive one. Further delay of this measure would be inappropriate and unjustified.

<sup>17</sup> Chapter VIII and Appendix.

<sup>18</sup> E.g., Robert Doyle, Tr. 116; David Gezon, Tr. 1273; Louis Gross, II, Jr., Texas Independent Automobile Dealers Association, R. 53; Marvin G. Levin, President, Professional Remodelers Association of Greater Chicago, R. 1364.

<sup>19</sup> E.g., Ira J. Lefton, Tr. 668; Warren J. McEleneay, Tr. 1234; Robert Serafine, Tr. 1089; Leonard M. Cohen, General Counsel, Independent Finance Association of Illinois, R. 1376.

<sup>20</sup> E.g., Eugene W. Hart, Tr. 694; James J. Schintz, Texas Independent Auto. Dealers, R. 55; Michael Larson, Marine National Exchange Bank of Milwaukee, R. 58.

<sup>21</sup> E.g., David Gezon, Tr. 1274; Louis Gross, Tr. 385; J. Manly Head, Tr. 1140; Warren J. McEleneay, Tr. 1288; Leonard Cohen, R. 1377; Jack S. Watson, Pennsylvania banker, R. 372.

<sup>22</sup> Tr. 1279.

<sup>23</sup> R. 370.

<sup>24</sup> R. 6011-6048.

<sup>25</sup> Tr. 1502.

<sup>26</sup> See notes 4 and 5, *supra*. Also, Ira J. Lefton, Tr. 668; E. D. Cartwright, Pennsylvania banker, R. 88.

<sup>27</sup> David Gezon, Tr. 1277; Ira J. Lefton, Tr. 685; L. A. Roseberry, Tennessee banker, R. 67; Leonard Cohen, R. 1377.

<sup>28</sup> R. 55.

<sup>29</sup> E.g., George Jones, Tr. 1507-09.

<sup>30</sup> E.g., Robert Doyle, Tr. 1137; Helen Nelson, Tr. 720.

<sup>31</sup> Tr. 549-50; see also Helen Nelson, Tr. 720.

<sup>32</sup> Jack Watson, Pennsylvania banker, R. 372.

<sup>33</sup> Wisc. Ann. Code 110.3 (1970).

<sup>34</sup> Hart, Tr. 695.

<sup>35</sup> Tr. 696.

<sup>36</sup> Tr. 705-706. Mr. Hart also attributed some of the decline to the 3-day cooling-off period requirement. Finally, when asked whether National Marine Bank's drop from \$400,000 to \$50,000 was due primarily to Wisconsin's restriction on the holder-in-due-course doctrine (promulgated one year before the hearings), Mr. Hart responded, "Well, this has been over a period of ten years. There's been a gradual diminution" (Tr. 710).

<sup>37</sup> E.g., Tr. 387-390 Louis Gross, Boulevard Loan Company, New Jersey; Tr. 1272 (David Gezon, Volkswagen American Dealers Association); R. 81 (Cessna Finance Corp.); R. 1377 (Independent Finance Association of Illinois); R. 1640-41 (Richard P. Schaumann for Indiana Automobile Dealers Association); 1651-53 (Robert Holland, Ohio National Bank of Columbus); R. 1660-61 (Connecticut Credit Union League, Inc.); R. 1667-69 (Keith Nelson for Mercantile Credit Corp.) "The burden of such policing is really tremendous . . ." R. 1703 (Don H. Reavis for bank of the Southwest, Amarillo, Texas); R. 1707 (Roland Bartson, Bell Federal Savings, Chicago); R. 1912 (Consumer Bankers Association), R. 2524 (John F. Cline, Minneapolis).

<sup>38</sup> E.g., Hart, Tr. 691; Gross, Tr. 382; Doyle, Tr. 1108.

<sup>39</sup> Magnuson and Carper, *The Dark Side of*

See footnotes at end of chapter.



the Marketplace 86 (1968). Information [in brackets] updated to June, 1972, by interview with Mr. Stansbury of the Property Improvement Office of FHA, by telephone, June 28, 1972. At the time the quoted material was written (1968), the number of firms on the Precautionary Measures List was "over 7,000". The number declined by approximately 30% over the years 1968-72, which period also marked a time of significant activity in the legislatures of about twenty states in enacting restrictions upon the holder in due course doctrine. Indeed, many of the statutes are specifically aimed at home improvements.

<sup>2</sup> E.g., Hart, Tr. 705; Robert B. Evans, National Consumer Finance Ass'n., Tr. 1709; Richard P. McManus, Household Finance Corp., Tr. 2024; Bill W. Dixon, Wisconsin Installment Bankers Ass'n., Tr. 2154.

<sup>3</sup> Eugene W. Hart, Vice President, Marine National Exchange Bank, Milwaukee, Tr. 705.

<sup>4</sup> Tr. 2154-55.

<sup>5</sup> Tr. 2024-2025.

<sup>6</sup> UCC 3-417 (2) (d). The comment to this provision states: "The position is taken that the buyer does not undertake to buy an instrument incapable of enforcement, and that in the absence of contrary understanding the warranty is implied. Even where a buyer takes as a holder in due course who will cut off the defense, he still does not undertake to buy a lawsuit with the necessity of proving his status." Of course, the mere existence of this warranty makes it harder for consumers to defeat "holder" status.

<sup>7</sup> Tr. 427.

<sup>8</sup> [Statistics assembled by the National Commission on Consumer Finance confirm Prof. Kripke's assessment. See National Commission on Consumer Finance, "Consumer Credit in the United States" 36 (1972).]

<sup>9</sup> E.g., Eugene W. Hart, Tr. 691; Prof. William F. Willier, Tr. 1033; Lawrence R. Buxbaum, Attorney General's Office, Commonwealth of Massachusetts, Tr. 1300; Jim Smith, Senior Vice President, Security Pacific National Bank, California, Tr. 1437; Robert B. Evans, Maryland, Tr. 1707; John S. Hinkley, National Automobile Dealers Association (Utah), Tr. 1794; McManus, Tr. 2023-47; Larson, Tr. 2123-45; Bill W. Dixon, Tr. 2145-60; Richard Victor, Assistant Attorney General, Wisconsin Department of Justice, Tr. 2173-2181.

<sup>10</sup> Alan R. Feldman and Douglas Greer, "Creditors' Remedies and Contractual Provisions: A Legal and Economic Analysis of Consumer Credit Collections", Volume V of the National Commission on Consumer Finance Studies, summarized in Consumer Credit in the United States, Report of the National Commission on Consumer Finance, pp. 34-38 (Washington, 1972), hereafter cited "NCCF Report".

<sup>11</sup> Milton W. Schober, General Counsel, Douglas P. Greer, Economic Consultant, NCCF.

<sup>12</sup> Note, "A Case Study of the Impact of Consumer Legislation: The Elimination of Negotiability and the Cooling-Off Period," 78 Yale L. J. 613 (1969), where, at p. 655, it is concluded from the study that

"Eliminating negotiability makes fraudulent dealers bad credit risks, and thus induces financial institutions to be reluctant to take their notes. The findings of this study suggest that financiers impose important new restrictions on dealers which should reduce the extent of fraud in sales. On the other hand, the conservative reaction by most banks and finance companies to the elimination of negotiability in Connecticut has created another cost—widespread difficulty in marketing consumer paper. This apparent overreaction has resulted in higher charges to consumers and damage to legitimate businessmen. Whether these costs more than offset the benefits from restrictions designed to

penalize fraudulent dealers is impossible to calculate exactly."

<sup>13</sup> See notes 36-42(a) *Infra*.

<sup>14</sup> E.g., Hart, Smith, Evans, Hinkley, McManus, Larson, Dixon, note 31, *supra*.

<sup>15</sup> Jim Smith, Senior Vice President, Security Pacific National Bank, San Francisco, Tr. 1465-6.

<sup>16</sup> Tr. 1757-1758.

<sup>17</sup> Tr. 2174-756.

<sup>18</sup> NCCF Report, p. 36.

<sup>19</sup> Tr. 1594-95.

<sup>20</sup> Tr. 1595.

<sup>21</sup> It is significant that the N.C.C.F. recommended imposition of restrictions analogous to those contained in this rule, despite the predicted marginal diminution in aggregate credit. See N.C.C.F. Report at pages 34-38.

<sup>22</sup> Not With A Gun, Jean Carper (NY 1973).

<sup>23</sup> Fairfax Leary, R. 2073-2074.

<sup>24</sup> Tr. 1594, 1596.

<sup>25</sup> Tr. 2197-2200, 2203.

<sup>26</sup> E.g., Paul Daniel, Tr. 1252; Virginia H. Knauer, Tr. 900; Robert Serafine, Tr. 1034; Jim Smith, Tr. 1105; David C. Todd, Tr. 1180; American Industrial Bankers Association, R. 29.

<sup>27</sup> National Commission on Consumer Finance, "Consumer Credit in the United States" (Washington, 1972).

<sup>28</sup> Id. at 34-38.

<sup>29</sup> E.g., Milton W. Schober, Tr. 1517.

<sup>30</sup> Schober, Tr. 1616; Morris, Tr. 1701.

<sup>31</sup> See the testimony of Dr. Greer cited in footnote 46.

<sup>32</sup> E.g., Paul Daniel, Tr. 1253; Robert Doyle, Tr. 1109 1124; Louis Gross, Tr. 383; Eugene Hart, Tr. 694, 697; J. Manley Head, Tr. 1139-40; Warren J. McElenny, Tr. 1282, 1286; Robert S. Olson, Tr. 954, 960; James Schintz, Pennsylvania Independent Automobile Dealers Association, R. 55; Michael J. Larson, Marine Nat'l. Exchange Bank, Milwaukee, Wisconsin, R. 59.

<sup>33</sup> E.g., Ruth Charney, Tr. 459; Betty Furness, Tr. 34-35; Lester S. Goldblatt, Tr. 469; Virginia Knauer, Tr. 901; Fairfax Leary, Jr., Tr. 970; Bess Myerson, Tr. 365; Fred Speaker, Tr. 1027; David Swankin, Tr. 1372; William F. Willier, Tr. 1034, 1041; Robert Wagman, Chairman, Sandom Members United to Act, St. Louis, R. 1250; Robert Hadler, Legal Assistance Foundation of Champaign County, Illinois, R. 1294.

<sup>34</sup> E.g., Massachusetts, New York, New Jersey, Wisconsin. Interaction between statutory and decisional law probably makes California eligible for this list as well. The limited time that legislation has been effective in other jurisdictions makes evaluation difficult.

<sup>35</sup> E.g., Connecticut, Mississippi, Nevada, Texas, New Mexico.

<sup>36</sup> Massachusetts, New York, Maryland and the District of Columbia have explicitly closed this loophole.

<sup>37</sup> E.g., In California, the statute with the strongest protection excludes motor vehicle and home improvement sales; Connecticut (statute applied only to home solicitation sales); Delaware (excludes motor vehicle and home repair sales).

<sup>38</sup> Prof. Homer Kripke, Tr. 439; Robert S. Powell, Tr. 297.

<sup>39</sup> E.g., Wilbur Leatherberry, Tr. 1016; Wagman, Tr. 609; William Willier, Tr. 1034.

<sup>40</sup> The following witnesses testified that transactions often involve an out-of-state party: Jack Elendrath, Tr. 831; Julia Fuller, Tr. 929; Anthony Martin-Trigona, Tr. 910; Dennis J. Roberts, II, Tr. 420; Alan Sims, Tr. 214. See also note 67, *supra* p. 49.

<sup>41</sup> Dean W. Determan, Tr. 1006; Betty Furness, Tr. 42; Lester S. Goldblatt, Tr. 468-69; Howard I. Kaufman, Tr. 505; Virginia H. Knauer, Tr. 900; Homer Kripke, Tr. 440; Fairfax Leary, Jr., Tr. 970; Bess Myerson, Tr. 365; Helen Nelson, Tr. 721; Sarah H. Newman, Tr. 998; Edwin Palumbo, Tr. 413; Fred Speak-

er, Tr. 1027; Eve Widows, Tr. 94; William Willier, Tr. 1035; Views of the Atlanta Legal Aid Society, Tr. 23.

<sup>42</sup> E.g., Unico v. Owen, 50 N.J. 101, 232 A.2d 405 (1967); Commercial Credit Corp. v. Childs, 199 Ark., 1073, 137 S.W. 2d 160 (1940); Commercial Credit Corp. v. Orange County Mach. Works, 34 Cal. 2d 766, 214 P. 2d 819 (1950); Mutual Fin. Co. v. Martin, 63 So. 2d 65 (fla. 1953). Fairfield Credit Corp. v. Donnelly, 264 A.2d 547 (1969); Geiger Finance Co. v. Graham, 123 Ga. App. 771, 182 S.E. 2d 521 (1971).

<sup>43</sup> Judge Arthur Dunn, Tr. 770; Benny L. Kass, Tr. 1219; Homer Kripke, Tr. 438; Fairfax Leary, Jr., Tr. 969; Wilbur Leatherberry, Tr. 1016; Steven Mindell, Tr. 24; Agnes Ryan, Tr. 558; Alan Sims, Tr. 218.

<sup>44</sup> Many witnesses agree that a trade regulation rule would encourage rather than discourage further state action. E.g., Barbara Flicker, Tr. 407; Betty Furness, Tr. 32; Benny L. Kass, Tr. 1206; Steven Mindell, Tr. 29; Helen Nelson, Tr. 721; Stephen Schlossberg, Tr. 862; David Swankin, Tr. 1372; Cf. Robert S. Olson, Tr. 952; Rex Carpenter, Tr. 848, 852.

#### CHAPTER VII. WHAT THE REVISED RULE DOES AND WHY

Part One. *The purpose of this rule.* The Commission believes that it is an unfair practice for a seller to employ procedures in the course of arranging the financing of a consumer sale which separate the buyer's duty to pay for goods or services from the seller's reciprocal duty to perform as promised. The Commission's rulemaking procedures, which encourage broad participation on the part of interested parties and which result in a bright-line standard of conduct in appropriate cases, serve the three-fold interest of clarity, uniformity, and fairness to the regulated industry.<sup>1</sup> For this reason, where a Trade Regulation is found to be necessary and appropriate, any final rule must be as concise and straightforward as possible.

The final revisions of this rule reflect modifications for concision and coverage. As revised, the rule will prevent sellers from foreclosing consumer equities in credit sale transactions. It will prevent the use of direct-loan financing to accomplish the same end.

*Policy considerations.* In promulgating this rule for enactment the Commission has considered and resolved a variety of policy considerations. We will discuss these considerations here to place this rule in perspective.

Our primary concern, in the course of these proceedings, has been the distribution or allocation of costs occasioned by seller misconduct in credit sale transactions. These costs arise from breaches of contract, breaches of warranty, misrepresentation, and even fraud. The current commercial system which enables sellers and creditors to divorce a consumer's obligation to pay for goods and services from the seller's obligation to perform as promised, allocates all of these costs to the consumer/buyer. Consumers are generally not in a position to evaluate the likelihood of seller misconduct in a particular transaction. Misconduct costs are not incorporated in the price of the goods or services, nor are they reflected in any deferred payment

See footnotes at end of chapter.



price or unpaid balance of a sales-related loan. Seller misconduct costs are thus externalized in a way that renders many sales finance transactions inherently deceptive and misleading. In addition, to the extent that consumers are also compelled to bear the costs occasioned by the misconduct of another, while the "guilty" party avoids all liability, we believe that reliance on contractual foreclosures of equities in consumer transactions constitutes an unfair practice under Section Five of the F.T.C. Act.

The Commission believes that only when prices approach or approximate real social costs do consumer choices in the market tend towards an optimal allocation of society's resources.<sup>2</sup> Our objective then, in this rule, is two fold. First we would employ our remedial authority to modify existing commercial behavior such that the costs occasioned by seller misconduct in the consumer market are reduced to the lowest possible level in the retail distribution system. Second, where certain seller misconduct costs cannot be eliminated from the market we would require that such costs be internalized, so that the prices paid by consumers more accurately reflect the true social costs of engaging in a credit sale transaction.<sup>3</sup>

In the preceding chapters, we have discussed the nature and extent of seller misconduct costs which are allocated in all or part to consumers by means of discount financing and direct loan financing. We have also discussed the reasons why the current commercial system has these effects. Consumers are not in a position to police the market, exert leverage over sellers, or vindicate their legal rights in cases of clear abuse. The sheer expense of obtaining an accurate assessment of the likelihood of seller misconduct in a particular case are prohibitive. High-pressure sales tactics combined with documented misrepresentations in many lines of retail endeavor further reduce the likelihood that an individual buyer can successfully weigh the probability that a given transaction will spawn a claim or defense. Redress via the legal system is seldom a viable alternative for consumers where problems occur. Delays combine with the unpredictable results produced by the legal system to often result in increased harm for the consumer litigant.<sup>4</sup> Where a seller is sued, the consumer must undertake the further risk that his defendant will prove insolvent or unavailable on the day of legal reckoning.<sup>5</sup>

This rule approaches these problems by reallocating the costs of seller misconduct in the consumer market. It would, we believe, reduce these costs to the minimum level obtainable in an imperfect system and internalize those that remain.<sup>6</sup> As a practical matter, the creditor is always in a better position than the buyer to return seller misconduct costs to sellers, the guilty party. This is the reallocation desired, a return of costs to the party who generates them. The creditor financing the transaction is in a better position to do this than the consumer,

because (1) he engages in many transactions where consumers deal infrequently; (2) he has access to a variety of information systems which are unavailable to consumers; (3) he has recourse to contractual devices which render the routine return of seller misconduct costs to sellers relatively cheap and automatic; and (4) the creditor possesses the means to initiate a lawsuit and prosecute it to judgement where recourse to the legal system is necessary.

We believe that a rule which compels creditors to either absorb seller misconduct costs or return them to sellers, by denying sellers access to cut-off devices, will discourage many of the predatory practices and schemes discussed above in Chapter III. Creditors will simply not accept the risks generated by the truly unscrupulous merchant. The market will be policed in this fashion and all parties will benefit accordingly. Where applicable economies militate against a creditor effort to return misconduct costs to a particular seller, due to the limited or irregular nature of such costs, the rule would require the creditor to absorb such costs himself. That is, where a consumer claim or defense is valid, but limited in amount, a creditor may choose to accept less payment from the consumer to save transaction costs associated with pursuing the seller whose conduct gave rise to the claim. The creditor may also look to a "reserve" or "recourse" arrangement or account with the seller for reimbursement. In such cases, the price of financing will more accurately reflect the actual costs of sales finance.

In cases where "repurchase" or "reserve" contracts, or other recourse devices available to creditors, facilitate the return of an account to a seller, or whenever serious harm is occasioned by seller misconduct, the creditor will compel the seller to carry the costs so occasioned. Again, the result will be a more accurate price for consumer goods.

The Commission, in adopting this rule, is mindful of the fact that a regulation which requires creditors to either absorb seller misconduct costs or return them to sellers, may have the effect of imposing some buyer misconduct costs on sellers too. This could occur where a repurchase contract facilitates the disgorging of bad debts by returning them to the seller who generated them. It is probably true that creditors are more efficient collectors of bad debts than are sellers. Thus, a system which engenders an increase in the number of bad debts sellers must collect may yield a slight reduction in efficiency with respect to "consumer misconduct" costs.

We are persuaded that such diseconomies will be substantially outweighed by the benefits which will attend a reorientation which causes the market to absorb seller misconduct costs. Creditors and sellers are in a position to engage in meaningful, arms-length, bargaining over the terms contained in recourse arrangements. The Commission has received substantial evidence that such agreements are routinely employed in sales-finance transactions, and that the

provisions contained therein can be tailor-made to the needs of both parties. Such recourse contracts between sellers and creditors are constantly refined by the development and modification, based on experience, of reserve accounts which allocate risk and liability between the parties to correspond with actuarial assessments of risks.<sup>7</sup>

Section five of the F.T.C. act and the externalization of seller misconduct costs. The policy considerations discussed immediately above underpin our conclusion that the use of promissory notes, waivers of defenses, and vendor-related loan financing to foreclose consumer claims and defenses in credit sale transactions constitutes an unfair practice under 15 U.S.C. 45, as amended. It is unfair to subject an innocent party to costs and harm occasioned by a guilty party. Consumers are clearly injured by a system which forces them to bear the full risk and burden of sales related abuses. There can be little commercial justification for such a system. The desired reallocation of cost and risk will both reduce the costs of seller misconduct in the marketplace and return the residuum to the guilty parties. Consumers and honest merchants will benefit, as prices come to reflect actual transaction costs and honest merchants no longer need compete with those who rely on abusive sales practices.<sup>8</sup>

In announcing this rule, we are pursuing our statutory mandate to identify and prevent unfair or deceptive practices in the marketplace. This authority has been analogized by the United States Supreme Court to the jurisdiction of a commercial equity court.<sup>9</sup> We have thus weighed competing equities in the market in reaching our conclusion that the mechanical abrogation of consumer claims and defenses is unfair to consumers. We conclude that a consumer's duty to pay for goods or services must not be separated from a seller's duty to perform as promised, regardless of the manner in which payment is made. In reaching this conclusion we note thousands of instances, documented in the record of this proceeding, where the separation of what are normally regarded as reciprocal duties caused substantial injury to consumers. The common sense shock articulated by many of the consumer witnesses upon learning that their duty to repay a creditor was totally unrelated to their seller's promises is perhaps the clearest and most direct evidence of the injurious and distorted impact of the challenged practices.

Section Five of the FTC Act and Contracts of Adhesion. Furthermore, the Commission concludes that the economic injury to consumers discussed herein above results from terms contained in form contracts. Consumer witnesses and the many legal services groups who participated in the proceeding indicated repeatedly that promissory notes and waivers of defenses are inserted as boilerplate in installment agreements. They also stated that consumers rarely comprehend the significance of these devices at the time when the transaction is con-

See footnotes at end of chapter.



summated. Our detailed findings in this connection are set forth in Chapter III.

It is clear from the poll conducted by the Office of Economic Opportunity, and from statistics submitted by consumer groups and legal services offices, that the externalization of seller misconduct costs which causes substantial consumer injury is a function of an adhesive bargaining process. Promissory notes and waivers of defenses are presented to consumers on a take it or leave it basis. These contracts are drafted by sellers and creditors and they are not susceptible to modification at the point of sale.

The Commission believes that relief under Section five of the FTC Act is appropriate where sellers or creditors impose adhesive contracts upon consumers, where such contracts contain terms which injure consumers, and where consumer injury is not off-set by a reasonable measure of value received in return. In this connection, the Commission's authority to examine and prohibit unfair practices in or affecting commerce in the manner of a commercial equity court is appropriately applied to this problem.<sup>24</sup> Where one party to a transaction enjoys substantial advantages with respect to the consumers with whom he deals, it is appropriate for the Commission to conduct an inquiry to determine whether the dominant party is using an overabundance of market power, or commercial advantage, in an inequitable manner.

We have conducted the contemplated inquiry in this case. We have reached a determination that it constitutes an unfair and deceptive practice to use contractual boilerplate to separate a buyer's duty to pay from a seller's duty to perform. We are persuaded that this bifurcation of duties with its attendant externalization of costs injures both consumers and the market. We know of no substantial benefits which may be received by consumers in return for the valuable legal rights they are compelled to relinquish. We can imagine no reasonable measure of value which could justify requiring consumers to assume all risk of seller misconduct, particularly where creditors who profit from consumer sales have access to superior information combined with the means and capacity to deal with seller misconduct costs expeditiously and economically.

Our findings with respect to the use of vendor related loans to separate a consumer's duty to pay from his seller's duty to perform are detailed in Chapter IV. We are of the view that the use of direct loan agreements is no less adhesive than the use of installment sales contracts which incorporate waivers or promissory notes. We have received substantial evidence that sellers work cooperatively with lenders to foreclose consumer equities, and that such cooperation involves high-pressure sales tactics and deceptive and misleading statements. We have received substantial evidence that this rule would be seriously weakened by a failure to address the vendor related loan problem. We are

therefore persuaded that the reasoning appearing above in this chapter applies with equal force to direct loan financing, and that our rule must apply to "purchase money" loan transactions.

**Part Two. What the revised rule does.** What is meant by eliminating foreclosures of equities. This rule is directed at the preservation of consumer claims and defenses. It will require that all consumer credit contracts generated by consumer sales include a provision which allows the consumer to assert his sale-related claims and defenses against any holder of the credit obligation. From the consumer's standpoint, this means that a consumer can (1) defend a creditor suit for payment of an obligation by raising a valid claim against the seller as a set-off, and (2) maintain an affirmative action against a creditor who has received payments for a return of monies paid on account. The latter alternative will only be available where a seller's breach is so substantial that a court is persuaded that rescission and restitution are justified. The most typical example of such a case would involve non-delivery, where delivery was scheduled after the date payments to a creditor commenced.

Thus, the rule will give the courts the authority to examine the equities in an underlying sale, and it will prevent sellers from foreclosing judicial review of their conduct. Sellers and creditors will be responsible for seller misconduct. The courts will remain the final arbiters of equities between a seller and a consumer. However, the liability occasioned by the contract modification imposed by this rule should have two effects. First, it will impel creditors to exercise reasonable care in financing certain sales transactions.<sup>25</sup> Second, it will induce credit outlets to take certain mechanical steps to facilitate the process whereby a contract is returned to a seller for cause.

**Transactions to which this rule applies.** The Commission has carefully weighed the commercial circumstances which justify imposition of this rule. We have concluded that consumer credit obligations should be subject to claims and defenses whenever credit is arranged or secured in connection with a continuing relationship between a seller and a creditor. In such cases, for the purposes of Section Five of the FTC Act, seller and creditor may properly be viewed as joint venturers.<sup>26</sup> The basic rationale for the rule, namely that sellers should not avoid the costs occasioned by their misconduct and creditors are always in a better position than consumers to return misconduct costs, applies in any situation where sellers and creditors work cooperatively to finance consumer sales.

**Discount transactions.** The revised rule applies to all consumer discount transactions. Such transactions contemplate the routine assignment of consumer credit obligations to acceptance creditors. In many cases the creditor who purchases this paper also finances the seller's acquisition of inventory. A close and continuing relationship is thus the norm. The revised rule defines "Creditor" as a person who "finances the sale of

goods or services to consumers on a deferred payment basis". The words "Financing a Sale" are specifically tied to the Truth in Lending definition of "Credit Sale". The rule thus applies to all retail installment obligations affected by the Truth in Lending Act. A seller is a "Creditor" for the purposes of the rule whenever he executes a retail installment contract. In his capacity of seller and creditor, the seller is enjoined from taking or receiving a consumer credit contract, of any kind, which fails to contain the following provision:

#### NOTICE

ANY HOLDER OF THIS CONSUMER CREDIT CONTRACT IS SUBJECT TO ALL CLAIMS AND DEFENSES WHICH THE DEBTOR COULD ASSERT AGAINST THE SELLER OF GOODS OR SERVICES OBTAINED PURSUANT HERETO OR WITH THE PROCEEDS HEREOF. RECOVERY HEREUNDER BY THE DEBTOR SHALL NOT EXCEED AMOUNTS PAID BY THE DEBTOR HEREUNDER.

The rule expressly applies to credit contracts arising from sales of services, such as trade or vocational school agreements as well as sales of consumer tangibles. The record fully supports application of this rule to consumer service contracts.<sup>27</sup>

Our original proposed rule contained two distinct prohibitions in discount transactions. It required inclusion of a similar provision in any promissory note or other negotiable instrument taken in connection with a credit sale. It prohibited the use of waivers of defenses, rights, remedies, claims . . . etc. in connection with credit sales. The final version of the rule no longer draws a distinction between promissory notes and waivers. Instead of two prohibitions the rule contains only one, namely the requirement that the specified contract provision be inserted in all sale-related consumer credit contracts. Our definition of "Financing a Sale" makes it clear that the rule only applies to credit transactions within the meaning of the Truth in Lending laws. Our original prohibition on waivers would have applied to all sales, regardless of whether credit was involved. Such a prohibition would have affected warranties and other obligations which were not the subject of this proceeding.

Finally, by eliminating references to terms such as "negotiable" or "negotiable in form" we have simplified the rule. We have also avoided potential litigation in enforcement proceedings by eliminating consideration of the technical nature of a non-conforming contract.

**Vendor-related loan transactions.** The original rule proposed by the Commission did not look beyond discount or acceptance transactions. The rule was limited to installment sales contracts. This approach would have permitted widespread evasion of the rule.

Accordingly, as detailed in Chapter IV herein, we republished our proposed rule for additional hearings and comment with respect to the use of vendor-related loan financing. Our revised proposal contained a general definition of "Related Creditor" together with nine enumer-

<sup>24</sup> See footnotes at end of chapter.



ated fact situations which were to create a rebuttable presumption that a creditor was sufficiently close to a seller to justify imposition of the rule. Our original definition of "Related Creditor" was broadly formulated. It read as follows:

Any person, partnership, corporation, or association, except a credit card issuer with respect to his credit card operations, which is engaged in making loans to consumers to enable payment to be made for consumer goods or services, and which either participates in or is directly connected with the consumer transaction.

The nine specific fact situations which followed this definition are discussed in Chapter IV at pages 62-65. These specific criteria did not limit the scope of the above definition, but they were most useful in eliciting testimony on the myriad of different arrangements and relationships between consumer loan outlets and retail sellers which involve some continuing business relationship between the parties. Each of the criteria received specific support and documentation on the record.<sup>14</sup>

In preparing our final version of this rule the Commission has simplified and clarified its vendor-related loan provisions, taking full account of the information elicited during the second round of proceedings on the rule. The final version will afford the coverage which the record justifies with greater clarity and uniformity than our original proposal would have engendered. It will provide the Commission with a small degree of flexibility, in the same manner as the original proposal, while announcing a clear policy which is readily understood and easily followed.

To the extent that a lender is related to a seller by operation of the definition of "Purchase Money Loan", such a lender occupies a position which is functionally similar to that occupied by a discount creditor who purchases the seller's paper. Such lenders have the same access to information as discount creditors. The record strongly suggests that they may also obtain equivalent guarantees and endorsements from sellers which embody a "repurchase" obligation.

The final version of this rule contains no rebuttable presumptions. Operation of the rule, in this context, turns on the three related definitions of "Purchase Money Loan", "Contract", and "Business Arrangement", a creditor being defined as a "person who lends purchase money".

The words "Purchase Money Loan" are defined as "a cash advance which is received by a consumer in return for a 'Finance Charge' within the meaning of the Truth in Lending Act and Regulation Z, and which is applied, in whole or substantial part, to a purchase of goods or services from a seller who:

- (a) refers consumers to the creditor, or
- (b) is affiliated with the creditor by common control, contract, or business arrangement."

See footnotes at end of chapter.

The words "Contract" and "Business Arrangement" are defined to include all formal or informal arrangements and procedures which, based on this record, would justify imputation of an established and continuing course of dealing between a lender and a seller. These definitions will encompass all of the situations enumerated in the rebuttable presumption segment of our original rule, with the exception of the ninth which involved knowledge of a seller's reputation. We are not persuaded that knowledge alone suggests a course of dealing, even though questions of a creditor's knowledge are relevant to a determination of his relationship with a seller. Such a test should not be dispositive. It raises too many problems of proof.

We have retained the "referral" test originally proposed as one of the rebuttable presumptions. As proposed it specified five or more referrals to a creditor. Based on this record we are persuaded that while the act of referral is sufficient to justify imposition of the rule, provided referrals are made in the course of some routine or arrangement, there is no justification for choosing a specific number. Such a number would be arbitrary and unsupportable. There is no reason why five referrals render a seller's conduct intrinsically unfair where four do not. One seller may do business in a small town where the smallest number of referrals justifies imposition of the rule; another may do business in a large city where a larger number would be required to impose the rule. As a general proposition, we believe that this record supports the proposition that referrals by a seller make a creditor "related". The word is stated in the plural in the rule. Any seller who arranges financing for his customers should be prevented from cutting off claims and defenses by means of the financing so arranged.

The four definitions of "Creditor", "Purchase Money Loan", "Contract", and "Business Arrangement" will reach every situation where a seller and a lender may be said to work cooperatively to finance consumer sales. We believe that the record in this proceeding supports application of the rule to all situations where concerted or cooperative conduct between sellers and creditors is employed to facilitate the retail distribution of goods and services to consumers. This is true without regard to the "type" of credit, loan or discount, which is used. The revised rule goes exactly this far and no further.

We have eliminated the "rebuttable presumption" mechanism because it is unnecessary. The Commission, after review of the comments and testimony received during this proceeding, has defined the situations it desires to reach. Presumptions may be appropriate absent adequate information; however, a presumption in this rule would work to encourage continuing litigation when enforcement efforts were made. A presumption would thereby engraft many of the undesirable features of adjudication onto a Trade Regulation Rule. It would encourage inconsistent results in

successive enforcement proceedings, where one party extinguished the presumption and another failed to do so. It would contribute to continuing uncertainty and unjustified costs and delay in enforcement. As we noted at the outset of this Chapter, a Trade Regulation Rule should serve the threefold interest of uniformity, fairness and clarity.

Finally, in revising the provisions of the rule which are aimed at vendor-related loan transactions we have clarified the practice which is prohibited. The revised rule declares it an unfair practice within the meaning of Section Five for a seller to accept, as full or partial payment for any sale or lease of goods or services, the proceeds of a "Purchase Money Loan", unless any consumer credit contract which is made or taken in connection with the loan contains the following provision:

#### NOTICE

ANY HOLDER OF THIS CONSUMER CREDIT CONTRACT IS SUBJECT TO ALL CLAIMS AND DEFENSES WHICH THE DEBTOR COULD ASSERT AGAINST THE SELLER OF GOODS OR SERVICES OBTAINED WITH THE PROCEEDS HEREOF. RECOVERY HEREUNDER BY THE DEBTOR SHALL BE LIMITED TO AMOUNTS PAID BY THE DEBTOR HEREUNDER.

Sellers will thus be prevented from relying on vendor-related loan financing to avoid the other prohibitions contained in this rule. The most logical and concise way of accomplishing this end, in the text of a rule, is to prohibit the specific conduct which is challenged. For this reason we have focused this provision of the rule by applying a direct prohibition on the acceptance of loan proceeds as payment for a sale. Our original proposal did not specify what was to constitute the unfair practice beyond the act of "engaging in a sale".

By simplifying the definitions, focusing our operative language, and eliminating the broad general definition of "related creditor", we have narrowed our vendor-related loan proposal to correspond with what was learned in this proceeding. We have also revised our vendor-related loan provision so that it functions in a manner analogous to the balance of the rule.

The revised rule will require no consumer notice. Many consumers and consumerists urged the Commission to include a requirement in this rule that a notice be attached to pertinent legal documents employed in credit sales transactions to apprise consumers of their legal rights. We received significant evidence that many consumers simply fail to read their contracts. There was therefore a continuing concern expressed that consumers might forfeit the benefits conferred by the rule, more or less by default.

The industry opposed any detailed consumer notice with vigorous assertions that the actual text of the document proposed by FTC staff was extremely antibusiness in tone. In this respect, certain consumer groups agreed that consumer education notices, prepared



for comment in the proceedings, were probably too inclusive in scope to be fair to the industry.<sup>18</sup>

In our view, the most persuasive case for imposing an additional burden on the industry in the form of a mandatory notice to accompany all consumer credit contracts used in credit sales was made by witnesses who discussed the problems of Spanish-speaking Americans in the course of the New York hearings.<sup>19, 20, 21</sup> These comments and testimony were supported by the testimony of various representatives of the Consumer Federation of America.<sup>22</sup> The Commission is persuaded that Spanish speaking Americans are more readily victimized by unscrupulous merchants and creditors. The Commission agrees that Spanish speaking Americans have more difficulty in comprehending and vindicating their legal rights.

However, despite the unique problems of Spanish speaking Americans, we are not prepared to impose a consumer notice requirement on sellers and creditors at this time. Any such requirement would involve duplication and attachment of a complex, two-page, document to all related sales contracts and forms. The contents of such a document could be construed as incorporated by reference in a sales agreement, where this was not the Commission's intention. Conversely, the contents of such a document might mislead consumers into relying on apparent legal rights which were ultimately not vindicated by the courts. The purpose of the rule is to permit courts of competent jurisdiction to examine the equities where a consumer has a claim against a seller. The rule thus prevents foreclosures of equities by various means of financing a sale, but it does not impose any other requirements on the parties. Finally, the simple duplication and annexation of a notice similar to the one proposed would involve considerable expense for sellers and creditors.

The rule requires sellers and creditors to include a simple "notice" in the text of every consumer credit contract which is connected with a sale of goods or services. The notice must appear in ten point bold face type. While the wording of the notice is legalistic, we believe that it will be understood by most consumers.

The Commission also anticipates a substantial consumer education effort on the part of its staff after enactment of this rule. We will direct our staff to take reasonable action via the media to publicize the existence of the rule and what it means to consumer buyers. Announcements directed at the Spanish community will appear in the Spanish language. As legal services offices, consumer groups, and individual consumers test the rule by periodic lawsuits against creditors and sellers, and as the courts thus become more receptive and accustomed to considering competing equities in consumer sale transactions, the rule will enjoy increasing knowledge and use on the part of all consumers. We will monitor developments in this regard, and

we will take further action if special problems develop.

<sup>18</sup>Natl. Petroleum Refiners Assoc., et al. v. F.T.C., 482 F.2d 672 (DC Cir. 1973). Also see 1 Davis, *Administrative Law Treatise* 6.15 (1970).

<sup>19</sup>C. Ferguson, *Microeconomic Theory*, 391-92 (1966).

<sup>20</sup>Id.

<sup>21</sup>Littlefield, "The Plight of the Consumer in the Uniform Consumer Credit Code," 48 *Denver L. J.* 18 (1971); and "Preserving Consumer Defenses in Credit Card Transactions," 81 *Yale L. J.* 1 (1971).

<sup>22</sup>Commercial Credit Plan v. Beebe, 123 Vt. 317, 187 A.2d 502 (1963); Gross v. Appelgren, 467 P.2d 789 (Colo. 1970); Norman v. World Wide Distributors, 202 Pa. Super. 53, 195 A.2d 115 (1963); also see cases cited in Reply Brief for Appellants at 22 and 23, *Payne v. United California Bank*, 100 Cal. Rptr. 672 (1972).

<sup>23</sup>See, e.g., G. Calabresi, *The Costs of Accidents* (1970) which contains a detailed explanation of this kind of analysis.

<sup>24</sup>The Commission has received copies of many such agreements in the course of this proceeding and related investigations. See Chapter VI, *supra* at note 29.

<sup>25</sup>See the discussion appearing in F.T.C. v. Curtis Publishing 78 FTC 1472, 1515 (1971) where the anticompetitive impact of permitting an unscrupulous merchant to retain unlawful gains may be a factor in determining that his conduct violates Section Five. Also see, *FTC v. Algoma Lumber*, 291 U.S. 67 (1934); *Interstate Home Equip. Co.* at 40 FTC 260 (1945); and *FTC v. Winsted Hosiery*, 258 U.S. 483 (1922) where similar theories are discussed.

<sup>26</sup>See *Sperry and Hutchinson v. FTC*, 405 U.S. 233, 244 (1972).

<sup>27</sup>*Sperry and Hutchinson v. FTC* *supra* note 9.

<sup>28</sup>Some courts have already taken steps to impose a duty of care, albeit a limited one, on creditors who willingly finance dubious sales transactions. See e.g., *Connor v. Great Western Savings & Loan Assoc.*, 69 Cal. 2d 850, 447 P.2d 609 (1968). While the S & L in this case took an active role in the financing of a residential development, and while this role included actively participating in the project, many consumer lenders are active and willing participants in sales transactions, offering "specials" for favored customers and suggesting borrowings for summer sales and Christmas gift needs. In such cases, the duty of care imposed in *Connor* seems highly appropriate.

<sup>29</sup>A joint venturer is defined as one who seeks a specific profit jointly with another, in a particular transaction. *Ditcher v. Booth*, 13 N.J. Super. 568, 571, 80 A.2d 648, 650 (1951). Also see e.g., *Uniform Partnership Act*, Sec. 13-15. Coventurers or partners are generally liable for each others' acts on their behalf. A joint venture may arise with no formal arrangement. It may be imputed inferentially. *Cooperstein v. Shapiro*, 122 N.J. Eq. 238, 192 A.2d 828 (1937).

<sup>30</sup>Forham, Tr. 626-28 (represented twenty-one students who had enrolled in a computer training school that went out of business and who were under pressure from various financial institutions to continue making payments); John Keller, Office of the Superintendent of Public Instruction, Illinois, Tr. 562-70 (his office has jurisdiction over 300 private business and vocational schools in Illinois and he cites two typical student complaints); Mindell, Tr. 19 (recent case where computer school went out of business); John C. Neubauer, Consumer Education & Protection Organization, Des Moines, Iowa, Tr. 622; Ronald Pritsch, Chicago Legal Aid Bu-

reau, Tr. 743-44 (modeling-school case in Cook County); John P. Preloznik, Director, Wisconsin Judiciary, Tr. 553; Phyllis Senegal, Legal Aid Society of Gary, Indiana, Tr. 638-39 (two cases involving a karate school); Scholl, Tr. 1177; Ryan, Tr. 556-57; Ralph S. Stone, Chief Attorney, Consumer Law Unit, Legal Aid Society of St. Louis, R-1327. Examples of consumer's experiences: Tr. 51-55, 617-19; R. 100, 101, 111, 1672, 1679, 1684, 1686, 1712. Ryan, Tr. 557. Patricia Hynes, Tr. 250, suggested that the definition "include a specific reference to services purchased by an individual to aid him or her in earning a livelihood". Such language has the advantage of encompassing fees charged by employment agencies (R. 1153-58), but the Commission considers the language overly broad for the purposes of this Rule.

<sup>31</sup>See footnotes 13-31 in Chapter IV, *supra*.

<sup>32</sup>Lawrence R. Buxbaum, Tr. 1313; Teresa Clark, Tr. 925; Barbara Flicker, Tr. 406; Richard Huffman, Tr. 89-90; Patricia Hynes, Tr. 252; Benny L. Kass, Tr. 1203; Gladys Kessler, Tr. 1059; Fairfax Leary, Jr., Tr. 981; Suzanne Matsen, R. 284, 291; Bess Myerson, Tr. 369; Dennis J. Roberts II, Tr. 417.

<sup>33</sup>E.g., Benny L. Kass, Tr. 1203; Gladys Kessler, Tr. 1059; Suzanne Matsen, Tr. 284, 291; Wilbur Leatherberry, Tr. 1022; Bess Myerson, Tr. 369.

<sup>34</sup>E.g., Hinckley, Tr. 1803; Bernard Davis, R. 5984-85.

<sup>35</sup>E.g., James Lattner, Legal Aid Society, Chicago, Tr. 2326.

<sup>36</sup>Sarah Negron, Tr. 51-55, R. 895-897; Jose Suarez, Tr. 47-51, R. 900-901; Victor Tice, Tr. 210-212, R. 898-899.

<sup>37</sup>Rose Ferreira, R. 585-586; Amada Ortiz, R. 594-596; Aida Luz Nieves, R. 597-599.

<sup>38</sup>E.g., Huffman, Tr. 82: "... T/he Spanish-speaking [clients] I had in the South Bronx were at a much greater disadvantage than other minority groups. The Spanish-speaking clients were generally easily swayed by interpretations of what the written English [on a contract] says." Lester E. Goldblatt, Legal Aid Society of New York, Tr. 474; Thos. Eovalid, Chicago Council of Lawyers, Tr. 2186.

<sup>39</sup>E.g., Williams, Tr. 70-71; Huffman, Tr. 90; Kessler, Tr. 1050 (Consumer Federation of America).

#### CHAPTER VIII. DISCUSSION AND DISPOSITION OF SUGGESTED ALTERNATIVES AMENDMENTS OR REVISIONS TO THE RULE

A. Limit consumer to defense or setoff. Many industry representatives suggested that the rule be amended so that the consumer may assert his rights only as a matter of defense or setoff against a claim by the assignee or holder.<sup>40</sup> Industry representatives argued that such a limitation would prevent the financier from becoming a guarantor and that any limitation in the extent of a third party's liability was desirable.<sup>41</sup>

The practical and policy considerations which militate against such a limitation on affirmative actions by consumers are far more persuasive. For example, Professor Egon Guttman, Professor of Law at American University and a member of the District of Columbia Ad Hoc Committee on Consumer Protection, stated at the hearings that such a limitation:

May affect the credit rating of the consumer who, although he is under recent legislation entitled to demand the erasure of improperly determined credit ratings, may still find that his present needs for credit could have been affected by his refusal to pay a debt arising under a retail installment sales transaction.<sup>42</sup>

See footnotes at end of chapter.



Professor Guttman went on to say that the right to recover against an assignee "is nothing new in the law . . . Where does the right of financial institutions arise to make them different from the rest of the people?"

California's Unruh Act which makes an assignee "subject to all claims and defenses of the buyer against the seller" but provides that the buyer may assert his rights only "as a matter of defense to a claim by the assignee,"<sup>2</sup> has recently been interpreted by the California Supreme Court.<sup>3</sup> In a consumer class action seeking rescission of the plaintiffs' installment contracts, the assignee-finance companies claimed that the plaintiffs could not bring an affirmative action against them. The California Supreme Court disagreed, stating:

The finance companies contend that under this section [of the Unruh Act] plaintiffs may not bring an affirmative action against them for rescission but may only assert their defense of fraud in an action by the finance companies to collect on the contracts and then only to the extent of the amount still owing. Upon analysis, however, a number of considerations militate against such a restrictive interpretation. . . .

The purpose of the Unruh Act is to protect consumers, and it should be liberally construed to that end. (Morgan v. Reesor, 69 Cal. 2d 881, 889.) If we were to adopt the concept of the finance companies it would . . . bestow upon them immunities and privileges against consumers unavailable to them in the ordinary commercial transaction. (Cf. *Unico v. Owen* (N.J. 1967) 232 A.2d 405, 417-418.)

It is suggested by *amicus curiae* that Section 1804.2 was intended to eliminate the possibility that by depriving assignees of any right to take free of the buyer's defenses against the seller despite an agreement to the contrary, the section might subject assignees to products liability suits which might involve personal injuries and large damage claims.

It would be ironic indeed if a provision in an act intended to benefit consumers could be invoked to their detriment to such an extent that they would stand in a less advantageous position than others in the commercial arena. . . . If, despite the allegations of the complaint—admittedly true on demurrer—we were to adopt the view of the finance companies, we would be according to financial institutions greater commercial advantage against consumers than they enjoy with reference to all others. Such a result cannot be justified.<sup>4</sup>

At the New York hearings Bess Myerson, Commissioner of the New York City Department of Consumer Affairs, discussed the New York statute which limits the consumer to a defense or setoff and stated, "without the right to initiate suit, . . . consumers are denied a basic weapon of protection against unresponsive third parties to installment credit contracts."<sup>5</sup> Another reason for not limiting consumers to a defensive position is that a stronger potential consumer remedy will encourage greater policing of merchants by finance institutions.<sup>6</sup>

The most persuasive reason for not limiting a consumer to a wholly defensive position is the situation referred to in Professor Guttman's testimony. A consumer may stop payment after unsuccessful

attempting resolution of a complaint with the seller, or he may have finally discovered that the seller has moved, gone out of business or reincorporated as a different entity. During this period the consumer may have been making payments to the financier in good faith, notwithstanding the prior existence of defenses against the seller.

If the consumer stops payment, he may be sued for the balance due by the third party financier. The financier may, however, elect not to bring suit, especially if he knows that he would be unable to implead the seller and he knows the consumer's defenses may be meritorious. Under such circumstances the financier may elect to not sue, in the hopes that the threat of an unfavorable credit report may move the consumer to pay.

Finally, it is important to remember that the contract provision this rule will require can only be enforced between the parties in a court of competent jurisdiction. The purpose of this rule is to mandate judicial scrutiny of a credit sale transaction, when a bona fide dispute develops between buyer and seller. The various cut-off devices discussed in this statement foreclose judicial review of the equities in such transactions. Consumers will not be in a position to obtain an affirmative recovery from a creditor, unless they have actually commenced payments and received little or nothing of value from the seller. In a case of non-delivery, total failure of performance, or the like, we believe that the consumer is entitled to a refund of monies paid on account.

**B. Set maximum amount.** Some industry representatives suggested that high price sales should be exempted from the rule for two reasons. First, the consumer who buys a high priced "luxury" item such as an airplane or a boat is generally more sophisticated than the average consumer and, therefore, is likely to read and understand the legal consequences of his contracts.<sup>7</sup> Second, the seller of such items relies on immediate sale of consumer installment contracts in order to replenish his costly inventory. If the market for this paper becomes tighter industry contends that many of these sellers would be driven out of business.<sup>8</sup> This assertion rests on assumptions about the alleged difficulty of assigning notes in the absence of cut-off devices. The weaknesses of these arguments have been examined above.<sup>9</sup> The price of a house full of furniture, an automobile, certain home improvements or other necessity items purchased by average consumers often exceeds the \$2,500 or even the \$5,000 urged by industry spokesmen as an upper limit to the rule. The rule should protect the rights of middle income consumers as well as low income consumers.<sup>10</sup>

The basis for the rule is a finding that reliance on various cut-off devices is an unfair practice under Section 5 of the FTC Act. The practice does not cease to be unfair simply because it involves a larger amount of money.

**C. Limitation upon the time in which defenses can be raised.** Some witnesses

urged the Commission to adopt a rule which would set a limit upon the time in which a consumer could raise defenses and which would require the consumer to notify the third-party financier of any defenses within the specified period.<sup>11</sup> The suggestion is similar to the "complaint period" approach adopted in several state laws.<sup>12</sup>

The "complaint period" approach, touched upon earlier, requires the assignee of a consumer instrument to give notice to the consumer of the transfer and of the consumer's right to raise defenses or make claims within a set period—usually 10, 15 or 30 days. It has been suggested that even the most shoddy merchandise will stand up for 15 or 30 days, and that the complaint period will be of little use.<sup>13</sup> More fundamental is the criticism advanced by several commentators and witnesses in this proceeding—that any "complaint period" approach suffers several fatal flaws:

(i) It is reported that the financiers' "notices" reach consumers buried in the midst of various junk mail<sup>14</sup> and that few, if any, consumers understand the requirement of the affirmative act of properly drafting and sending the notice.<sup>15</sup>

(ii) The fact of "non-complaint" may put the assignee holder in an even stronger legal position than he occupies under current law. "This kind of statute appears to give . . . an assignee as impregnable a legal position as one holding free of defenses by specific statutory mandate."<sup>16</sup>

Thus, for the uninformed, unsophisticated, or uneducated consumer—the person most in need of aid—the "complaint period" approach is unacceptable. The simple expedient of a delaying mechanism does not make a fundamentally unfair practice any less objectionable. The basic unfairness of the use of cut-off devices in consumer transactions remains after the expiration of the complaint period—be it five days or ninety.

**D. Miscellaneous suggestions.** The following revisions were suggested but found no substantial support in the record:

1. That consumer goods covered by an adequate warranty be excluded from the coverage of the rule.<sup>17</sup> The problem with this suggestion is two fold. It would be difficult to identify "adequate warranties" in this context.<sup>18</sup> In addition, the worst retailers go to great extremes to conclude sales. Frequently they misrepresent the actual warranty a consumer receives, in the course of getting the consumer to close the deal. This suggestion would leave the consumer with a substantial debt to a creditor and uncertain redress pursuant to a warranty.

2. That the rule's protection be extended to include small businessmen.<sup>19</sup> Such an extension would undermine a basic premise of the rule—that consumer transactions are essentially different from commercial transactions and the holder in due course doctrine originated in and is only appropriate for the latter. The need for such an extension of cov-

<sup>2</sup> See footnotes at end of chapter.



erage is not demonstrated on the record for this proceeding.

3. That the consumer be required to make a written demand upon the seller before stopping payments.<sup>2</sup> In most cases a consumer will attempt to resolve complaints with the seller before stopping payment. Specifying in the rule the manner in which such consumer/seller negotiation must take place would introduce unnecessary formality into the procedure. The format of such efforts should remain flexible. The Commission is also concerned that formalistic requirements upon the consumer would serve to create other problems, especially of proof—e.g., did the seller in fact receive notice?

4. Other miscellaneous suggestions and recommendations included: (i) expanding the rule to provide a comprehensive regulatory provision covering product warranties;<sup>3</sup> (ii) expand the rule to include a ban on confessions of judgment or cognovit notes;<sup>4</sup> (iii) proposals for a "Federal Credit Loss Insurance Corporation" and a "Consumer Credit Arbitration Service";<sup>5</sup> and (iv) a proposal to ban "sewer service" of court papers.<sup>6</sup> In each case the Commission has rejected these proposals as being outside the scope of the instant rule. The Commission takes no position on the merits of these suggestions. They are more appropriate for separate consideration.

<sup>1</sup> E.g., Eugene Hart, Tr. 712; Ira J. Lefton, Tr. 672-73; Robert Olson, Tr. 949-50; Robert Serafine, Tr. 1095; Max Denney, R. 28; Statement of American Bankers Association, et al., R. 1809-10.

<sup>2</sup> For example, Robert Olson stated that the rule "should not . . . provide the consumer with a new remedy, affirmative relief against an innocent third party assignee. A financial institution may be quite willing to accept the risk that the receivable it purchased from the seller is uncollectable because of some defect in the sale transaction. That same financial institution, however, would be most unwilling to become a guarantor of the seller's performance." Tr. 950.

<sup>3</sup> Tr. 1320.

<sup>4</sup> Tr. 1321.

<sup>5</sup> Cal. Civ. Code § 1804.2 (West Supp. 1971).  
<sup>6</sup> Vazquez v. Superior Court of San Joaquin County, 94 Cal. Rptr. 796, 484 P.2d 964 (1971).  
<sup>7</sup> Id. at 823-24, 484, p.2d at 979-80, 94 Cal. Rptr. at 811-12 [footnotes omitted].

<sup>8</sup> Tr. 363. Steven Mindel, Assistant Attorney General with the Bureau of Consumer Frauds and Protection in New York also criticized the New York statute on this point.

"So the statute, in effect, on the one hand gives him rights and on the other hand says, you can't use these rights as a sword; you have to use them as a shield. It seems to me there is absolutely no justification for this second limitation. It puts the consumer in the guise of defendant. It doesn't permit him to go forward effectively when he feels that he may justifiably do so." Tr. 14.

<sup>9</sup> Frank Cochran, Tr. 238-39.

<sup>10</sup> E.g., David C. Todd, National Association of Engine and Boat Manufacturers, Tr. 1180; E. D. Chase, President, Cessna Finance Corporation, R. 81-82.

<sup>11</sup> E.g., Jim Smith, Tr. 1136; David C. Todd, Tr. 1181.

<sup>12</sup> Pages 78-92, *supra*.

<sup>13</sup> E.g., Barry Balme, Tr. 1187; Arthur Roddey, New Jersey consumer who describes the problems he had with a contractor to

construct a swimming pool, Tr. 100. See also R. 64-65 (swimming pool).

<sup>14</sup> Hart, Tr. 698; Lefton, Tr. 672-3; Olson, Tr. 949; Todd, Tr. 1182.

<sup>15</sup> Murray, "The Consumer and the Code: A Cross-sectional View", 23 Univ. of Miami L. Rev. 11, 65 (1968). See also C. Katz, ed., *The Law and the Low Income Consumer* 249-51 (1968).

<sup>16</sup> Jordan and Warren, "The Uniform Consumer Credit Code", 68 Columbia L. Rev. 387, 434-435.

<sup>17</sup> Kripke, "Consumer Credit Regulation: A Creditor-Oriented Viewpoint", 68 Colum. L. Rev. 455, 473 n. 75 (1968).

<sup>18</sup> Murphy, "Lawyers for the Poor View the UCCC", 44 N.Y.U. Rev. 298, at 310 (1969).

<sup>19</sup> Jordan and Warren, *supra* n. 16, at 435.

<sup>20</sup> David Gezon, Tr. 1276-77; Warren J. McKenney, Tr. 1291.

<sup>21</sup> Delzer, New Jersey Consumer, Tr. 422; Betty Furness, Tr. 38; Anthony Martin-Trigona, Tr. 907, 914.

<sup>22</sup> Robert S. Olson, Tr. 949; *contra*, Gladys Kessler, Tr. 1064; Ronald Fritsch, Tr. 741.

<sup>23</sup> Wendy Larson, Editor in Chief, St. Paul University Law Review, Tr. 1971-78, R. 6701-41.

<sup>24</sup> McCulloch, R. 3750.

<sup>25</sup> Robert D. Breth, Certified Consumer Credit Executive, R. 5945-47.

<sup>26</sup> Hartnell, R. 2877.

#### APPENDIX: PUBLIC COMMENT ON THE PROPOSED RULE

Specific submissions in the public record have been discussed or footnoted in the appropriate topic sections above. A few general remarks about the scope of the record are included here.

Submissions came from a great variety of sources. Support ranged from one-line postcards<sup>1</sup> to lengthy, heavily-documented legal submissions.<sup>2</sup> There are over two hundred submissions on the record from individuals—not identified with a group or business—which express general support for the rule.<sup>3</sup>

A number of individuals (in addition to those submitting personal case histories) wrote longer, more detailed letters in support of the rule.<sup>4</sup>

Federal, state and local government officials expressed approval of the rule.<sup>5</sup>

Two judges expressed support.<sup>6</sup> The Canadian Minister of Consumer and Corporate Affairs expressed approval of proposed Commission action,<sup>7</sup> and the Ministry supplied materials documenting the Canadian experience.<sup>8</sup>

Support for the rule was expressed by over one hundred consumer, labor and other associations and organizations.<sup>9</sup> Over thirty legal aid organizations are on record in favor of the rule.<sup>10</sup> A number of attorneys wrote as individuals, not on behalf of a client, in support of the rule.<sup>11</sup> Over one dozen educators wrote<sup>12</sup> or testified.<sup>13</sup>

Finally, the rule received strong support from a number of businessmen<sup>14</sup> and the backing of two bankers.<sup>15</sup>

Most opposition to the proposed rule was presented by businessmen, bankers and trade associations. There are also a number of letters opposing the rule submitted by individuals not identified as affiliated with a group or business.<sup>16</sup> Two public officials expressed disapproval.<sup>17</sup>

There are many letters in opposition from individual retailers, representing a variety of businesses.<sup>18</sup> Individual banks and bankers wrote to oppose the rule in fairly large numbers.<sup>19</sup> Finance companies are represented by submissions<sup>20</sup> including closely related finance companies.<sup>21</sup> Trade associations and similar organizations make up the bulk of

See footnotes at end of appendix.

the remainder of submissions in opposition.<sup>22</sup> By number, automobile dealers,<sup>23</sup> and banking or finance groups<sup>24</sup> predominate. Submissions were also received from credit card issuers and credit card associations.<sup>25</sup>

There are several letters expressing disapproval of the rule from attorneys not writing on behalf of a client bank or association,<sup>26</sup> and from the academic community.<sup>27</sup> Promulgated by the Federal Trade Commission November 14, 1975.

<sup>1</sup> E.g., "I strongly believe it is in the public interest to abolish the 'holder-in-due-course doctrine.' Thank you." H. Greenlee, Jr., R. 3453.

<sup>2</sup> E.g., Statement of Civil Rights—Civil Liberties Research Committee, Harvard Law School, R. 1482-1515.

<sup>3</sup> E.g., "... [I]f the seller and note holder both know that the law is on [the consumer's] side, the seller will make a better product that he can stand behind without fear." R. Stevens, R. 16; "Let us cease to legally screw the poor." Tony Scott, R. 78-79; "I realize that lenders will have to learn something about fair value of items, but don't you think that since the item is technically collateral that they should know what their collateral is really worth?" Arne Sampe, R. 348; "... one more thing we might do to help convince our young people there really is effective recourse for just grievances in America." Mrs. B. J. Parsons, R. 1587; "This ruling will give the consumer a little more assurance that the retailer will be as honest as he claims his product is good." Kenneth R. Parr, R. 2566; "I urge the Commission to abolish this antiquated and unconscionable practice." Rice Odell, R. 3442.

<sup>4</sup> E.g., Bycer, R. 1602-1604; Marcellino, R. 2535-2538; DiBlasio, R. 3390-3392.

<sup>5</sup> U.S. Representatives:

Hon. Henry B. Gonzales, R. 361-362.  
Hon. John M. Murphy, R. 998-1001.  
Hon. Abner J. Mikva, R. 2032-2034.  
Hon. Bella Abzug, Tr. 458-461.

Federal appointees:

Virginia H. Knauer, Special Assistant to the President for Consumer Affairs, Tr. 894-906, 1395-1413; R. 2040-2048, R. 6830-6842. See also R. 3388-3387.

Richard W. McLaren, Assistant Attorney General, Antitrust Division, United States Department of Justice, R. 1925-1988.

Deputy Assistant Attorney General, Bruce B. Wilson, Antitrust Division, United States Department of Justice, R. 1925-1988.

Thomas E. Kauper, Assistant Attorney General, Antitrust Division, United States Department of Justice, R. 7105-7128.

Whitney North Seymour, Jr., United States Attorney for the Southern District of New York, Tr. 242-272, R. 1006-1011.

State and local:

Florida: Robert J. Bishop, Director of Consumer Services, Department of Agriculture and Consumer Services, R. 5646. City of Jacksonville: Thatcher Walt, Consumer Affairs Officer, Division of Consumer Affairs, Department of Human Resources, R. 5671.

Georgia: James Mason, Office of Comptroller General, State of Georgia, R. 1720-1723.

Illinois: Howard I. Kaufman, Chief, Consumer Fraud Division, for Attorney General, State of Illinois, Tr. 497-512, 1885-1902; Michael K. Bakalis, Superintendent of Public Instruction, State of Illinois, by John Keller, Assistant, Tr. 562-570, R. 2510-2514. Milton Hirsch, Acting Supervisor, Consumer Credit Division, Department of Financial Institutions, Tr. 2052-2063.

Indiana: Richard Burdige, Administrative Assistant to Director, Department of Financial Institutions, Tr. 1997-2019.

Kansas: Vern Miller, Attorney General, R. 5644.



**Louisiana:** R. Collins Vallee, Special Counsel, Consumer Protection Unit, Department of Justice, R. 5475-76.

**Massachusetts:** Lawrence R. Buxbaum, Assistant Attorney General, Chief, Consumer Protection Division, Department of the Attorney General, Commonwealth of Massachusetts, Tr. 1300-1314.

**Minnesota:** Thomas J. Tahnk, Supervisor of Consumer Credit, Banking Division, Department of Commerce, Tr. 2196-2207, R. 7145-49.

**New Jersey:** Carl F. Flanchi, Department of Community Affairs, State of New Jersey, R. 1639.

**New York:** Louis J. Lefkowitz, Attorney General, State of New York, R. 1004-1005; see also Tr. 9-31. Betty Furness, Chairman and Executive Director, New York State Consumer Protection Board, Tr. 31-43, R. 1216-1219. Thomas J. Mackell, District Attorneys, Queens County, R. 1012-1016. Bess Myerson, Commissioner, New York City Department of Consumer Affairs, Tr. 360-382, R. 1017-1023. Anita De Gregorio, Administrative Assistant, Office of Consumer Affairs, County of Onondaga, R. 5483-5594, 5676.

**Oregon:** Roger Rook, District Attorney, Oregon City, R. 5333-34.

**Pennsylvania:** Joel Weisberg, Director, Division of Consumer Affairs, Commonwealth of Pennsylvania, R. 5255-56.

**Puerto Rico:** Maximiliano Trujillo, Assistant Secretary, Department of Consumer Affairs, Consumer Services Administration, R. 5272-73.

**South Dakota:** John S. DeVany, Commissioner of Consumer Affairs, Office of Attorney General, State of South Dakota, R. 3505-3506.

**Utah:** W. S. Brimhall, Commissioner of Financial Institutions, State of Utah, R. 57.

**Virginia:** William T. Lehnner, Assistant Attorney General, Division of Consumer Counsel, Office of Attorney General, Commonwealth of Virginia, R. 5262-63. Carl A. S. Coan, Jr., Chairman, Consumer Protection and Public Utility Commission, Fairfax County, R. 5605-07.

**Wisconsin:** Robert W. Warren, Attorney General, State of Wisconsin, R. 1755-1766, 5458-59. Hon. Harout O. Sanasarian, Wisconsin State Assemblyman, Tr. 510-526, R. 1224-1236. Daniel A. Milan, Director, Bureau of Consumer Protection, State of Wisconsin, Tr. 526-540. Richard Victor, Assistant Attorney General, Office of Consumer Protection, Department of Justice, State of Wisconsin, Tr. 2173-2181.

**Hon. Edward Thompson, J.S.C., Administrative Judge, Civil Court of the City of New York ("collective approval" of the proposed rule expressed "on behalf of the 120 judges" of the Civil Court), R. 560-561 and 1654-1655. Hon. Arthur Dunn, Associate Judge, Circuit Court of Cook County, Illinois, Tr. 757-775.**

**Hon. Ron Basford, R. 1719.**

**R. 137-325 and R. 3528-3580.**

**E.g., Local 320, Office and Professional Employees International Union, R. 14; North Carolina Consumers Council, Inc., R. 328; Rhode Island Consumers' Council, R. 945-969; NAACP Legal Defense and Education Fund, National Office for the Rights of the Indigent, R. 978-986; Center for Analysis of Public Issues, Princeton, N.J., R. 987-997; United Auto Workers, R. 1301-1307; Leland Blabie Broadcasting Company, Tucson, Arizona, R. 2526-2527; consumer Advisory Council, Office of Consumer Affairs, Executive Office of the President, R. 3386-3387; Arizona Consumers Council, R. 3515-3520;**

**Minnehaha County Farmers Union, Sioux Falls, South Dakota, R. 2468.**

**E.g., Atlanta Legal Aid Society, Atlanta, Georgia, "Each year the Society's attorneys handle approximately 17,000 cases, of which about 35% are consumer problems . . . [M]any of these cases eventually involve litigation in which the holder in due course concept is an important factor." R. 20, plus two case histories, R. 21-23; "An analysis . . . makes one thing abundantly clear: the holder in due course concept is the very heart of these operations. For it is essential to the disreputable seller that he be able to realize payment and then flee (either by actually leaving the jurisdiction or by ceasing operation) before this deception becomes apparent." R. 23. "This office is prepared to deliver . . . over one hundred case histories involving unfair consumer notes with which we have come in contact within the last six months." Memphis and Shelby County Legal Services Association, Memphis, Tennessee, R. 1626-1627. "We are confronted almost daily with the harsh and inequitable effects of the holder in due course doctrine." Legal Aid Society of Metropolitan Denver, Colorado, R. 3344-3447.**

**E.g., R. 15, 91, 390, 1365, 1366, 1678.**

**E.g., "[T]hese will be additional steps to help clean up the inequities of the market place. There is no reason why the holder-in-due-course should assume no responsibility for performance." Stewart Lee, Chairman, Department of Economics and Business Administration, Geneva College, R. 17; John P. Diesterhof, California Institute of Technology, R. 1595; Prof. William Seeman, University of Cincinnati, R. 1680; Prof. Phoebe Harris, Mississippi State University, R. 2528.**

**Law professors Eovaldi (Tr. 784), Guttman (Tr. 1314), Kripke (Tr. 437), Leary (Tr. 967), Wagman (Tr. 600) and Willier (Tr. 1033).**

**E.g., "[Y]our proposed rule . . . is both excellent and long overdue. I have worked with a great many retailers and I speak from very intimate knowledge." Donald Von Rase, R. 7; "I have no personal axe to grind, but I have seen many of my employees and fellow workers gravely hurt by these contracts and feel that this protection is essential for the consumer." A. Kazanow, Treasurer, Long Transportation Co., R. 13; "As manager of a Credit Union I have seen many of our members 'taken in' . . ." Donn Ashcroft, R. 352; "[L]egal technicalities of this kind . . . are certainly doing a disservice to the free enterprise system." F. Kavil, President, Kavlico Electronics, Inc., R. 1683.**

**Alvin F. Friedman, Vice President, Amalgamated Trust and Savings Bank, Chicago, R. 1357-1361; R. L. Mullins, Chairman, The Wolfe City National Bank, Wolfe City, Texas, R. 3398-3399.**

**E.g., R. 1521; "I feel the . . . regulation would be harmful to the consumer rather than help them." Diana M. Bird, R. 2547, R. 2565.**

**Hon. John R. Rarick, United States House of Representatives, R. 2455-2456. Hon. Willard J. Moody, State Senator, Commonwealth of Virginia, R. 1645.**

**E.g., Hughes Motor Co., R. 51; Western Auto Associate Store, Farrant, Alabama, R. 61; O'Fallon Frozen Food Lockers, R. 389; Horace Terry Pontiac Co., R. 393; Lou Backrodt Chevrolet, R. 1390-1381; Bill Hull's Appliances, Inc., R. 1519; Sid's Appliance Centers, R. 1529; Carl's TV Sales and Service, R. 3423; Fiore Brothers, Inc., General Contractors, R. 3486.**

**E.g., First National Bank, Elkhart, Indiana, R. 52; First National Bank of McMinn County, Athens, Tennessee, R. 66-67; Farmers National Bank of Little, Pennsylvania, R. 69; Northwest Pennsylvania Bank & Trust Co., Oil City, Pennsylvania, R. 83; The Citizens Bank of South Hill, Virginia, R. 85; The Citizens Bank, Farmington, New Mexico, R. 96; First Bank of Immokalee, Florida, R. 1674; Citizens National Bank, Ennis, Texas, R. 2522; Webster Groves Trust Co., Webster Groves, Missouri, R. 3502; Marine National Exchange Bank, Milwaukee, R. 58-60; National Bank of Detroit, Michigan, R. 2496-2498.**

**E.g., Cessna Finance Corp., R. 81-82; Security Mutual Finance Corp., Decatur, Alabama, R. 95; Transamerica Financial Corp., R. 1648-1650; Household Finance Corp., R. 1728-1734; Budget Finance Plan, Los Angeles, R. 2026-2031.**

**E.g., General Electric Credit Corporation, R. 1989-1993; Ford Motor Credit Company, R. 2057-2070; General Motors Acceptance Corp., R. 2457.**

**E.g., Professional Remodelers Association of Greater Chicago, R. 1363-1364; National Institute of Locker and Freezer Provisioners, R. 1670-1671; National Association of Engine and Boat Manufacturers, R. 2296-2313; Georgia Tire Dealers and Retreaders Association, R. 3581-3582.**

**E.g., National Independent Automobile Dealers Association (R. 2189-2190) and Independent Automobile Dealers Associations of: Texas, R. 53-54; Pennsylvania, R. 55-56; Florida, R. 2544; Lubbock, Texas, R. 3478; Alabama, R. 3478; Alabama, R. 3526-3527. National Automobile Dealers Association (R. 2356-2366) and Automobile Dealers Associations of: Texas, R. 53-54; Pennsylvania, R. 55-56; Florida, R. 2544; Lubbock, Texas, R. 3478; Alabama, R. 3526-3527. National Automobile Dealers Associations of: Indiana, R. 1640-1644 and Dayton, Ohio, R. 2463-2464; Volkswagen American Dealers Association, R. 2350-2355.**

**E.g., Banking; American Industrial Bankers Association, R. 27-30; Illinois Bankers Association, R. 1690-1691; American Bankers Association, R. 1861-1862; Consumer Bankers Association, R. 1907-1924; District of Columbia Bankers Association, R. 2480-2485.**

**Finance: Independent Finance Association of Illinois, R. 1372-1379; National Consumer Finance Association (1,200 member finance companies), R. 1994-1997; Illinois Consumer Finance Association, R. 2021-2025.**

**Other: Connecticut Credit Union League, R. 1660-1661; United States Savings and Loan League, R. 1735-1736.**

**E.g., American Express Company, R. 1212-1215; Western States Bankcard Association, R. 1863-1906; Texaco, Inc., R. 2004-2005; Charge Card Association, R. 2476-2479; Carte Blanche Corp., R. 3404-3405.**

**E.g., "[W]hat you would be doing if you adopt this kind of regulation would be 'kill the goose that lays the golden egg' . . ." Tom Sealy, Esq., Stubbeman, McRae, Sealy, Laughlin & Browder, Midland, Texas, R. 87-90; Ugo F. Ippolito, Esq., Birmingham, Michigan, R. 97-98; Philip Dale Segrest, Esq., Montgomery, Alabama, R. 367-369; "I strongly urge you to curb and restrain this curious fascination for changing society by administrative ruling." Jon Oden, Esq., Amarillo, Texas, R. 1681.**

**E.g., Edward A. Dauer, Assistant Professor of Law, University of Toledo, Ohio, R. 3396-3397.**

[FR Doc.75-30759 Filed 11-17-75; 8:45 am]



## FEDERAL TRADE COMMISSION

[ 16 CFR Part 433 ]

PRESERVATION OF CONSUMERS'  
CLAIMS AND DEFENSES

Notice of Proceeding, Proposed Amendment to Trade Regulation Rule, Statement of Reason for Proposed Amendment, Invitation To Propose Issues of Fact for Consideration in Public Hearings, Invitation To Comment on Proposed Amendment

Notice is hereby given that the Federal Trade Commission, pursuant to the Federal Trade Commission Act, as amended, 15 U.S.C. Section 41, *et seq.*, the provisions of Part I, Subpart B of the Commission's Procedures and Rules of Practice, 16 CFR § 1.11 *et seq.*, and Section 553 of Subchapter II, Chapter 5, Title 5 of the U.S. Code, (Administrative Procedure) has initiated a proceeding for the promulgation of an amendment to the above referenced Trade Regulation Rule.

In accordance with the above notice, the Commission proposes to revise § 433.2:

§ 433.2 Preservation of Consumers' Claims and Defenses, Unfair or Deceptive Acts or Practices.

In connection with any Purchase Money Loan (as that term is defined in § 433.1) or any sale or lease of goods or services, in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, it constitutes an unfair or deceptive act or practice within the meaning of Section 5 of that Act, for a seller or a creditor, directly or indirectly, to take or receive a consumer credit contract which fails to contain the following provision in at least ten point, boldface type:

## NOTICE

ANY HOLDER OF THIS CONSUMER CREDIT CONTRACT IS SUBJECT TO ALL CLAIMS AND DEFENSES WHICH THE DEBTOR COULD ASSERT AGAINST THE SELLER OF GOODS OR SERVICES OBTAINED PURSUANT HERETO OR WITH THE PROCEEDS HEREOF. RECOVERY HEREUNDER BY THE DEBTOR SHALL BE LIMITED TO AMOUNTS PAID BY THE DEBTOR HEREUNDER.

(38 Stat. 717, as amended, 15 U.S.C. sec. 41 *et seq.*)

STATEMENT OF REASON FOR THE PROPOSED  
AMENDMENT

It is the Commission's purpose, in issuing this statement, to set forth its reason for the proposed amendment with sufficient particularity to allow and encourage informed comment. While this statement advert to issues of fact, law, and policy, it should not be interpreted as designating disputed issues of fact. Such designations shall be made by the Commission or its duly authorized Presiding Official in accordance with the Commission's Procedures and Rules of Practice.

The Commission has conducted lengthy public proceedings on the "holder in due course" doctrine and related problems in consumer sales transactions. Extensive testimony, data, and information were elicited in the course of the proceedings. On the basis of information contained in those proceedings, the Commission promulgated a TRR relating to the Preservation of Consumer's Claims and Defenses, 16 CFR 433. In that proceeding the Commission determined that it constitutes an unfair or deceptive act or practice for a seller to separate, by means of a form consumer credit contract, a buyer's duty to pay from the seller's duty to perform as promised, and that this practice is injurious to consumers and to the market as a whole.

While the proceedings on 16 CFR 433 were primarily concerned with the commercial conduct of sellers, the record contains detailed information about related commercial practices of creditors which causes the Commission to have reason to believe that many creditors are participants in the aforesaid practice, that it is unfair and deceptive for them to engage in the practice and that the proscriptions of the rule can more effectively be enforced if creditors are subject to its provisions. Therefore, in the interest of (1) encompassing within the rule all participants in the aforesaid practice whose participation is unfair or deceptive and (2) facilitating enforcement of the rule, the Commission hereby proposes the aforesaid amendment.

At issue in the instant proceeding are simply the questions of whether creditors participate in the aforesaid practice, whether it is unfair or deceptive for them to do so, and whether the rule could be more readily enforced if credi-

tors were made subject to it. The Commission is not, in this proceeding, reopening the question of the applicability of the rule to sellers.

INVITATION TO PROPOSE ISSUES OF FACT  
FOR CONSIDERATION IN PUBLIC HEARINGS

All interested parties are hereby given notice of opportunity to propose disputed issues of fact, in contrast to legislative fact, which are material and necessary to resolve. The Commission, or its duly authorized presiding official, shall, after reviewing submissions hereunder, identify any such issues in a Notice which will be published in the FEDERAL REGISTER. Such issues shall be considered in accordance with Section 18(c) of the Federal Trade Commission Act, as amended by Public Law 93-637, and in accordance with rules promulgated thereunder. Proposals shall be accepted until no later than January 15, 1976 by the Special Assistant Director for Rulemaking, Federal Trade Commission, Washington, D.C. 20580. A proposal should be identified as a "Proposal Identifying Issues of Fact-Holder in Due Course," and, when feasible and not burdensome, submitted in five copies. The time and place for public hearings will be set forth in a later Notice which will be published in the FEDERAL REGISTER.

INVITATION TO COMMENT ON THE PROPOSED  
AMENDMENT TO 16 CFR 433.2

All interested parties are hereby notified that they may also submit, to the Assistant Director for Rulemaking, Federal Trade Commission, Washington, D.C. 20580, such data, views, or arguments on any issues of fact, law, or policy, which may have some bearing on the proposed amendment. Written comments, other than proposals identifying issues of fact, will be accepted until forty-five days before commencement of public hearings, but at least until January 15, 1976. To assure prompt consideration of a comment, it should be identified as a "Holder in Due Course Comment" and, when feasible and not burdensome, submitted in five copies.

Issued: November 14, 1975.

By the Commission.

CHARLES A. TOBIN,  
Secretary.

[FR Doc.75-30760 Filed 11-17-75;8:45 am]



# **federal register**

**TUESDAY, NOVEMBER 18, 1975**



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**PART IV:**

**DEPARTMENT OF  
HEALTH,  
EDUCATION,  
AND WELFARE**

**Food and Drug Administration**



**HUMAN BLOOD AND  
BLOOD PRODUCTS**

**Collection, Processing and Storage**



## Title 21—Food and Drugs

## CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 75N-0240]

## PART 606—CURRENT GOOD MANUFACTURING PRACTICES FOR BLOOD AND BLOOD COMPONENTS

## PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

## Final Regulations for Collection, Processing and Storage

The Commissioner of Food and Drugs is issuing final regulations concerning good manufacturing practices for blood and blood components, effective December 18, 1975.

Proposed good manufacturing practices (GMP) regulations for the collection, processing, and storage of blood and blood components, intended to minimize the dangers of hepatitis in blood-based therapy and to assure the production of blood and blood components of uniform high quality throughout the nation, were published in the FEDERAL REGISTER of May 28, 1974 (39 FR 18614). The proposed regulations applied to all blood banks, transfusion facilities, plasma-pheresis centers, compatibility testing establishments and all other facilities that process blood or blood components regardless of whether they were intended for interstate or intrastate commerce use. Interested persons were given until August 26, 1974 to file written comments with the Hearing Clerk, Food and Drug Administration, regarding the proposal.

Ninety-five letters, some containing a number of comments, were received. Many general comments were addressed to statements in the preamble. Most of the substantive comments concerned various specific provisions of the proposed regulations and contained recommended changes. Many comments encouraged greater specificity. Others indicated that the scope and intent of the proposed regulations were misinterpreted. To promote clarity and specificity, numerous nonsubstantive changes have been made. One of these nonsubstantive changes is a redesignation of the proposal to conform to an agency-wide format for good manufacturing practice regulations. The section numbers as originally proposed and their corresponding redesignated numbers are as follows:

May 1974 Proposal:	Redesignated as
606.3.....	606.3
606.19.....	606.20
606.10.....	606.40
606.11.....	606.60
606.12.....	606.65
606.15.....	606.100
606.16.....	606.110
606.30.....	606.120
606.18.....	606.140
606.17.....	606.151
606.40.....	606.160
606.41.....	606.165
606.45.....	606.170

Throughout this preamble, the new section numbers have been used. The comments and recommendations re-

ceived and the Commissioner's conclusions concerning them are set forth below.

## GENERAL COMMENTS

1. Three comments strenuously objected to the phrase "good manufacturing practice" for the collection, processing, and storage of blood and blood components. It was argued that blood and blood components are not manufactured and are not subject to sales taxes or implied warranties as are "manufactured" products. Rather, blood is produced by the donor and made available to the recipient. It was suggested that more appropriate terminology be used in place of the phrase "current good manufacturing practice."

The Commissioner advises that the term "manufacture" is applicable to blood and blood components. Blood is manufactured by the human body and requires further processing before it can be safely transfused into a recipient.

Blood intended for use in the diagnosis, cure, mitigation, treatment, and prevention of diseases in man is a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)). Section 501(a)(2) of the act (21 U.S.C. 351) states, in part, that a drug shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing and holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practice to assure that such drug meets the requirements of the act.

In addition, blood is specifically identified as a biological product subject to regulation pursuant to the Public Health Service Act (42 U.S.C. 262). Section 351 (a) (1) of this act uses the term "propagated or manufactured and prepared" for all biological products, including blood and blood components. The term "manufacture" is defined, in part, in § 600.3(u) (21 CFR 600.3(u)) to mean all steps in the propagation of manufacture and preparation of products. The biologics regulations prescribe requirements concerning all aspects of the manufacture of blood even before it is removed from the donor; e.g., §§ 640.3 and 640.63 (21 CFR 640.3 and 640.63) concern criteria for donor suitability.

Accordingly, the Commissioner rejects the comments, and the term "good manufacturing practices" remains in the regulation, consistent with existing terminology in applicable laws and regulations.

2. One comment objected to the classification of blood transfusion as a human tissue transplant on the basis that the science and technology of tissue and organ transplants differ fundamentally from blood transfusion. Three comments objected to the classification of blood as a drug.

The Commissioner rejects these comments. Blood is considered a tissue by the scientific community and is classified as such by most histology textbooks. As has been set forth at length in the preamble to the proposal for these regulations and

in the final order concerning registration of intrastate blood banks, published in the FEDERAL REGISTER of January 31, 1973 (38 FR 2965), blood is unquestionably a drug within the meaning of the Federal Food, Drug, and Cosmetic Act. The comments provide no information or data as a basis for the Commissioner to reconsider the classification of blood as both a tissue and a drug. Accordingly, no changes are made in the classification of blood as identified in the preamble of the proposal.

3. Three comments implied that post-transfusion hepatitis cannot be controlled by promulgating the proposed regulation, but rather by developing consistently accurate methods to detect hepatitis B surface antigen (HBsAg) in blood, which is the cause of posttransfusion hepatitis in blood recipients.

The Commissioner recognizes that promulgation of good manufacturing practice regulations alone may not completely eliminate the incidence of post-transfusion hepatitis. The Commissioner has concluded that these regulations, together with the final order published in the FEDERAL REGISTER of July 15, 1975 (40 FR 29706) requiring hepatitis testing of a third generation sensitivity, will significantly reduce the incidence of post-transfusion hepatitis. Moreover, these regulations are also designed to assure the production of blood of uniform high quality, and it is well recognized that properly controlled processing procedures are a first and basic step to accomplishing this purpose.

4. Two comments suggested that Food and Drug Administration (FDA) inspections be waived whenever a blood establishment has been inspected by non-government organizations such as the American Association of Blood Banks (AABB), the College of American Pathologists, or the Joint Commission on Accreditation of Hospitals.

The Commissioner advises that section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) requires that the FDA inspect intrastate establishments that process drugs, including blood products. The biologics regulations require that interstate manufacturers of all biological products be inspected prior to the issuance of a license. Neither of these provisions authorizes delegation of inspection responsibilities to a nongovernment organization. Furthermore, the Commissioner concludes that independent inspection of establishments by both the FDA and nongovernment organizations will promote safety and will help to assure a high quality product. Accordingly, the Commissioner rejects these comments.

5. Two comments noted that the proposed regulations are more general in tone than the standards of the AABB. The comments suggested that the FDA accept the AABB standards in their entirety or that the FDA regulations and the AABB standards be combined, since the standards of the AABB already have achieved national, if not world wide, acceptance.

As indicated in the preamble of the proposal, the Commissioner intends that



the proposed regulations be applicable to blood banks, transfusion facilities, plasmapheresis centers, compatibility testing establishments and any facility that processes blood and blood components. To anticipate standards of operation for any facility that processes blood and blood components, the proposed GMP regulations must of necessity be broader in scope than the standards of the AABB, which are directed primarily to blood banks and transfusion services. Accordingly, the Commissioner rejects these comments. The Commissioner notes, however, that § 606.100(d) *Standard operating procedures* provides that AABB manuals may be utilized consistent with the standards and guidelines established by these regulations.

6. One comment suggested that the proposed regulations be divided into two sections, the first to apply to blood banks and the second to blood depositories.

The Commissioner concludes that the proposed division of the regulations would not enhance clarity or promote the intent to assure the manufacture of products that are safe, pure, potent, and effective. Accordingly, the comment is rejected.

7. One comment stated that FDA should give priority to updating existing outdated regulations for products currently subject to its regulatory control before promulgating these new regulations.

The Commissioner concludes that priority must be given to amendments on the basis of their potential impact on the protection of the public health. These final regulations are of primary importance since they implement the provisions of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act for the first time for all blood establishments to assure that all blood and blood components on the market are safe, pure, potent, and effective. Moreover, the quality of currently marketed licensed products is sufficiently high under existing regulations to protect the public. And while the Commissioner recognizes that certain existing regulations need updating, an ongoing review of these regulations has resulted in recently published final orders and/or proposals regarding hepatitis testing of third generation sensitivity, platelet concentrate, normal serum albumin, plasma protein fraction and other blood products.

8. One comment noted that the preamble of the proposal requires that products meet all applicable standards prescribed in the biologics regulations. As a result, it was pointed out that the 28-day storage of blood approved by the State of Massachusetts conflicts with the 21-day dating period prescribed in § 610.53 (21 CFR 610.53) for Whole Blood (Human) collected in anticoagulant citrate phosphate dextrose solution (CPD). The comment suggested that the satisfactory experience obtained by the State of Massachusetts from its use of the 28-day storage period should be used as a basis for changing the 21-day dating period prescribed in § 610.53.

The Commissioner believes that a maximum dating period of 21 days for Whole Blood (Human) is practical and necessary to assure that only fresh whole blood is available for therapeutic use. Extension of the dating period would encourage storage of blood for an additional 7 days. Furthermore, the Commissioner has been advised that an amendment to the Massachusetts regulation is currently pending to reduce the storage period to 21 days. Accordingly, the comment is rejected.

#### DEFINITIONS

9. Two comments stated that a number of the requirements prescribed in proposed §§ 606.65, 606.100, 606.120 and 606.151 are not applicable to the manufacture of in vitro diagnostic products. For this reason, the comments suggested that the definition of "blood" in proposed § 606.3(a) be amended to exclude products intended as in vitro diagnostic reagents and that separate regulations be promulgated for them.

The regulations are generally applicable to all blood products, including in vitro diagnostic products. Significantly, proposed §§ 606.65, 606.100, 606.120, and 606.151 provide exemptions for requirements not applicable to in vitro diagnostic and other nontransfusion blood products. Accordingly, the Commissioner finds that separate regulations for in vitro diagnostic products are not necessary and no change is made in § 606.3(a) as proposed.

10. One comment concerning proposed § 606.3(b) stated that the definition of "unit" could be 5 to 10 milliliters. The comment gave no indication of an objection to the definition.

The Commissioner confirms that a unit would include volumes of 5 to 10 milliliters. Such small volumes are occasionally obtained from donors and infused into infants, often without antecedent testing for HBsAg or a serological test for syphilis. Additionally, small volumes of blood are used for the hyperimmunization of antiserum donors. The Commissioner concludes that infants and antiserum donors should receive the high standard of protection offered by the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. Accordingly, the definition of a unit includes any volume of blood used for transfusion, and such blood is subject to the applicable requirements of the regulations.

11. Two comments requested that the regulations be amended to permit plateletpheresis and leukopheresis procedures. These comments are discussed in item 49 of this preamble. Concomitant with the Commissioner's response to these comments, § 606.3 of the final regulations has been amended to include definitions for plateletpheresis and leukopheresis in paragraphs (f) and (g), respectively; proposed paragraphs (f), (g), and (h) are redesignated (h), (i), and (j) in the final order. Additionally, § 606.100(b) (17) has been added in the final regulation to require that the Standard Operations Procedure Manual describe the

plateletpheresis and leukopheresis procedures used.

12. One comment stated that the definition of processing in proposed § 606.3(g) (redesignated § 606.3(i)) is not consistent with the customary use of the term in blood banking, i.e., the term does not ordinarily include procedures prior to the collection of blood, the collection of blood itself, or compatibility testing.

The Commissioner recognizes that the term has vernacular connotations in blood banking. Accordingly, the definition of processing has been modified in the final regulation to be consistent with the customary use of the term in blood banking.

13. One comment indicated that proposed § 606.3(h) (redesignated § 606.3(j)) inferred that compatibility tests are synonymous with cross-matching. The comment stated that compatibility tests include, but are not limited to, crossmatching.

The Commissioner does not intend to infer that compatibility tests are synonymous with crossmatching. The term "crossmatching" was added for clarity, since some blood banks use the term "crossmatching" while others use the term "compatibility test" when referring to the same serological test. However, since there appears to be confusion in the interpretation of the paragraph, the Commissioner has deleted reference to the term "crossmatching" in the final regulation.

#### PERSONNEL

14. Six comments concerning the introductory paragraph of proposed § 606.20 suggested that the entire operation of a blood facility be under the direction of a qualified licensed physician and not a designated qualified person as prescribed in the proposed regulation. The comments stated that since blood banking is the practice of medicine, only a physician is qualified to direct a blood establishment.

The Commissioner intended that the qualified person be required to exercise control of the blood establishment consistent with the responsibility prescribed in § 600.10 (21 CFR 600.10) for a "responsible head". While the regulations do not exclude a physician from exercising these responsibilities, the Commissioner believes that nonphysicians with adequate training and experience are capable of performing such responsibilities. Past records of licensed establishments indicate that blood establishments having a nonphysician as the responsible head perform as well as those establishments having a physician as the responsible head. The Commissioner recognizes that certain responsibilities must be performed or supervised by a qualified licensed physician. Concomitantly, the regulations reflect such requirements in §§ 640.3, 640.61 and 640.62 (21 CFR 640.3, 640.61 and 640.62). Accordingly, the Commissioner rejects the comments. However, the Commissioner has revised the paragraph to clearly reflect the responsibilities of the person designated as director of the establishment. Additionally, the intro-



ductory paragraph has been designated paragraph (a). The proposed paragraphs (a) and (b) have been redesignated paragraphs (b) and (c) respectively.

15. Four comments concerning proposed § 606.20(a) (redesignated as § 606.20(b)) requested that the personnel qualification requirements be specified in the regulation.

The Commissioner intends to conduct a review of qualification requirements imposed by blood establishments for their medical and technical staff. Upon completion of the review, the Commissioner will be in a position to make practical, specific recommendations concerning personnel qualifications requirements. In the interim, each blood establishment must continue to establish its own standards and training requirement consistent with the basic requirements of skills and knowledge of assignments set forth in these regulations. Accordingly, the comment is rejected.

16. Eight comments concerning proposed § 606.20(b) (redesignated § 606.20(c)) requested clarification concerning persons whose presence can adversely affect the safety and purity of the products. The comments especially indicated concern that the regulation might exclude hepatitis B surface antigen carriers from working in a blood establishment.

The Commissioner is not aware of any data that would implicate transmission of hepatitis B surface antigen to donors or blood products by personnel who are carriers of the antigen under the customary conditions of performance of their duties. Consequently, such personnel are not expected to adversely affect the safety and purity of the products, and it is not intended that they be excluded from areas of blood processing. Rather, the regulation is intended to exclude from the processing area, persons who may distract the attention of clinicians or technicians from the performance of their duties and persons who, by their very presence in the processing area, are capable of affecting the safety and purity of the product. Examples of the latter include personnel moving from the HBsAg testing area to the processing area without taking necessary precautions and persons known to have contagious respiratory ailments. The Commissioner believes that the regulation is clear and precise. Accordingly, the comments are rejected and no change is made in the final order.

#### FACILITIES

17. One comment concerning proposed § 606.40(a) (2) requested further clarification of the phrases "adequate space", "minimal exposure" and "unrelated activities."

The Commissioner utilized these phrases to indicate that the facility's space must be conducive to the safety of the donor and the manufacture of a product that is safe, pure, potent and effective. More specific phrases were not used because the regulations are applicable to any facility that processes blood and blood components, and it is impossible to specify the exact size, location,

arrangement, lighting and equipment requirements without information concerning the specific process, number of donors, etc. For clarity, however, the Commissioner has changed the phrase "unrelated activities and equipment" to "activities and equipment unrelated to blood collection."

18. Two comments requested that proposed § 606.40(a) (3) be amended to require space for quarantine storage only for blood or blood components that give questionable serological test results. The comments suggested that there is no need to hold products in quarantine storage pending completion of all tests, as proposed.

The intent of quarantine storage is to isolate those units of blood and blood components that have been identified as potentially hazardous. Isolation assures that such products will not be used accidentally. The Commissioner agrees that untested blood should not be categorized as having the same safety risks as tested blood yielding questionable test results. The Commissioner concludes that untested blood and blood components need not be held in quarantine storage. Accordingly, § 606.40(a) (3) has been revised and a new paragraph (a) (4) has been added in the final regulation to differentiate storage space requirements for tested and untested blood. The proposed paragraphs (a) (4) through (a) (8) have been redesignated (a) (5) through (a) (9), respectively.

19. The Commissioner has also amended proposed § 606.40 by adding the word "quarantine" to the beginning of proposed paragraph (a) (5) (redesignated as paragraph (a) (6)) to be consistent with the discussion of the comment in item 18 of this preamble concerning the storage of products that may be potentially hazardous. Similarly, proposed paragraph (a) (6) (redesignated paragraph (a) (7)) has been amended consistent with the discussion in item 12 of this preamble concerning the definition of processing.

20. One comment suggested that proposed § 606.40(b) be clarified to indicate whether the word "screening" in the phrase "screening of open windows and doors" is intended to mean visual screening.

The Commissioner has used the word in its common or usual sense in association with doors or windows; namely, a partition, usually of wire or plastic mesh, to protect the facility from insect or rodent infestations. The Commissioner concludes that paragraph (b) adequately conveys this meaning. Accordingly, the comment is rejected and no changes are made in the final regulation.

21. Two comments concerning proposed § 606.40(c) suggested that the requirement to provide handwashing facilities in work areas could be interpreted to require that each work area, whether large or small, must have its own handwashing facility.

The Commissioner intends that handwashing facilities be convenient for personnel. However, the Commissioner recognizes that the paragraph may be mis-

interpreted as suggested in the comment. Accordingly, § 606.40(c) of the final regulation more clearly conveys the Commissioner's intent.

22. One comment interpreted proposed § 606.40(d), concerning the safe and sanitary disposal of trash and items used during processing of blood and blood components, as not contemplating anything more than proper disposal through the local refuse disposal system. The comment suggested that if anything further is required, the proposed rule should be republished in specific terms for further opportunity for comment.

The Commissioner advises that trash and other items used during the collection, processing, and compatibility testing of blood and blood components must be disposed of in a safe and sanitary manner. To ensure safe and sanitary disposal, all potentially infectious material must be autoclaved, incinerated, or otherwise sterilized to preclude contamination of the environment. These procedures do not require special or extraordinary disposal systems and no further publication with an opportunity for comment is warranted. Additionally, the Commissioner notes that the proposal did not specifically require the safe and sanitary disposal of blood and blood components found to be unsuitable for use. However, it is consistent with the obvious intent of the regulation, that such blood and blood components, likewise, should be discarded in a safe and sanitary manner to protect the public from the potential hazard that could be caused by introducing infectious material into the public waste disposal systems. Accordingly, § 606.40(d) of the final regulation more specifically identifies those items requiring safe and sanitary disposal.

#### EQUIPMENT

23. Five comments concerned the requirement in proposed § 606.60 that equipment be calibrated or tested on a regularly scheduled basis. Three comments requested, for clarity, examples of equipment requiring calibration or testing and the frequency at which they must be calibrated or tested. Two comments objected to the requirement on the basis that certain equipment cannot be calibrated because the design characteristics are not made available by the manufacturer of the equipment.

The Commissioner accepts the comments requesting clarification of the requirement. Accordingly, § 606.60 in the final regulation provides a list of examples of equipment to be calibrated, including the characteristics of the equipment to be calibrated, such as weight, temperature, speed, etc., and the frequency of calibration. The objection that certain equipment cannot be calibrated or tested on a regularly scheduled basis because the design characteristics are not made available by the manufacturer is rejected by the Commissioner. The use of accurate and reliable equipment is essential to ensure compliance with the requirements for the manufacture of products that are safe, pure, potent and



effective. For this reason, the Commissioner concludes that all equipment used in a blood establishment must meet the specifications for producing the intended effect in the manufacture of blood and blood components. To assure that any piece of equipment is operating properly, it must be tested on a regular basis and adjusted when necessary. If the equipment is faulty and cannot be repaired by the blood establishment, it must not be used by the blood establishment until repaired by other sources, or the piece of equipment may be replaced with one found to operate as required.

24. One comment suggested that proposed § 606.60 be amended to delete the phrase "official requirements" because official requirements for equipment have not been established.

The Commissioner intended that the phrase "official requirements" relate not to equipment, but rather to requirements such as weight, temperature, etc., prescribed for products in the regulations for blood and blood products. Accordingly, § 606.60 in the final regulation clarifies the intent of the phrase "official requirements."

25. Three comments concerning proposed § 606.60 suggested exempting from the sterilization requirement, disposable material that is already sterile when purchased by the blood establishment.

The Commissioner agrees that there is no need to resterilize disposable material that is sterile when purchased, and the regulations do not require that such material be resterilized. Furthermore, the subject regulation concerns equipment rather than material. Accordingly, no change is made in the regulation.

#### SUPPLIES AND REAGENTS

26. The title of proposed § 606.65 has been changed in the final regulation from "Materials" to "Supplies and reagents" for clarity and specificity.

One comment concerning § 606.65(a) suggested that an appropriate method be recommended for confirming pyrogenicity of supplies, such as blood container and donor sets, which the manufacturer claims are pyrogen free.

The Commissioner believes that ultimate responsibility for the claim that supplies are pyrogen-free should rest with the manufacturer of the supplies and not with the blood establishment. Accordingly, the comment is rejected and no special reference is made in § 606.65 (a) to a method for determining pyrogenicity.

27. One comment concerning proposed § 606.65 expressed concern regarding the requirement that all final containers for blood and blood components not intended for transfusion be made of material that will not interact with their contents to affect adversely the safety, purity, potency and effectiveness of the product. It was suggested that FDA inspectors might demand proof that the final container does not interact with its contents.

The Commissioner advises that with respect to containers for blood and blood products intended for transfusion or for further manufacture into injectable

products, substantial evidence establishing the safety and effectiveness must be submitted to the FDA by the manufacturer of the container for premarketing clearance. However, final containers for blood and blood components not intended for transfusion or for further manufacture of injectable products only need to be clean and free of surface solids and other contaminants and are not subject to premarketing clearance and approval by FDA. These exemptions do not apply when there is any possibility of the collected blood, or any part thereof, being returned to the donor.

28. One comment concerning proposed § 606.65(b) suggested that, in addition to the required inspection of containers prior to use, the container also be visually inspected for damage or evidence of contamination immediately after filling.

The Commissioner recognizes that a small puncture and certain types of contamination will be more evident after the container is filled. Accordingly, he accepts the suggestion and has added a provision to § 606.65(b) concerning visual inspection of containers immediately after filling.

29. Three comments concerning proposed § 606.65(b) noted that discoloration of certain collection and satellite containers is normal after sterilization. The comments suggested that the requirement concerning discoloration of the container either be deleted or revised to reference abnormal discoloration.

The Commissioner agrees that a certain amount of discoloration in plastic containers is normal and does not indicate a substandard container. Accordingly, the Commissioner accepts the suggestion and has amended § 606.65(b) by qualifying the word "discoloration" with the word "abnormal."

30. Ten comments concerning proposed § 606.65(c) objected to the requirement that representative samples of solutions or reagents susceptible to contamination be tested on a regularly scheduled basis to determine freedom from bacteria. It was argued that, generally, sterility of such unopened products is guaranteed by the manufacturer and therefore should not require further testing by the blood establishment. Additionally, it was noted that a vial of solution or reagent is normally used more than once. Consequently, some contamination of an opened vial is inevitable.

The Commissioner agrees that the manufacturer of the solution or reagent should be responsible for the sterility of an unopened product. Furthermore, the Commissioner recognizes that the usual contamination of an opened vial of solution or reagent will not seriously affect its potency or effectiveness. The purpose of the regulation is to ensure potency and effectiveness of solutions and reagents. Such assurance is obtained by the additional requirement in the same paragraph that samples of solutions or reagents liable to changes in concentration be tested on a regularly scheduled basis to determine their strength. In view of the testing for reagent reactive qualities provided by the regulations, the Commis-

sioner has concluded, on balance, that the requirement concerning sterility testing may be deleted from § 606.65(c).

31. Two comments concerning proposed § 606.65(c) expressed dissatisfaction with the need to assay solutions or reagents periodically for changes in concentration. One comment suggested that examples be given of solutions and reagents to be tested.

The Commissioner concludes that regularly scheduled testing of solutions and reagents for concentration is necessary to ensure adequate effectiveness of these products. Such testing is particularly important after storage or intermittent periods of use when the product can be expected to lose some of its reactive qualities. Quantitative tests need not be employed to demonstrate the capacity of the reagent to perform as required. Rather, suitably chosen control procedures may be used, provided such procedures are adequately described in the blood establishment's Standard Operating Procedures Manual. Accordingly, the final regulation retains the requirement to test regularly solutions and reagents to determine their concentration. However, to promote clarity and specificity, § 606.65(c) has been amended to provide a list containing reagents and solutions that shall be tested on a regularly scheduled basis and the required frequency of testing.

32. One comment interpreted proposed § 606.65(d) (now incorporated into § 606.160) to include the requirement that results of visual inspection of blood containers be recorded. The comment stated that it is unnecessarily burdensome to maintain such records and that only defects of containers need be recorded.

The Commissioner finds that the interpretation of the paragraph is incorrect. The intent of the proposed regulation is not to record the condition of each blood container, but rather to record the identity and disposition of containers that are not suitable for use. To clarify the requirements concerning records, the Commissioner has provided in § 606.160 a comprehensive list of records that must be maintained by the blood establishment.

33. Four comments concerning proposed § 606.65(d) (1) (redesignated § 606.160(b) (7) (v)) objected to the requirement for maintaining records of the lot number, expiration date, and date of receipt of each type of supply or reagent received from each manufacturer.

The Commissioner concludes that such records are necessary, together with processing records and compatibility records, to investigate and resolve problems that may arise from the use of faulty reagents or supplies employed in the manufacture of blood and blood components. Accordingly, the Commissioner rejects the comments and no change is made in § 606.160(b) (7) (v).

34. Four comments concerning proposed § 606.65(d) (2) (redesignated § 606.160(a) (2)) indicated that the requirement to keep specific records relating the lot numbers of reagents and sup-



plies to the final product requires an unnecessary amount of documentation.

The Commissioner advises that records must be kept to identify the reagent and other material employed in the production of each lot or unit of final blood product. However, the commentor apparently interpreted § 606.65(d)(2) as requiring that the lot numbers of reagents and supplies employed in the production of a final product be recorded in a specific manner such as a log book. No one format for these records is specified. Rather, as prescribed in § 606.160(a)(2), appropriate records must be available from which to determine the lot number of reagents and supplies used for specific lots or units of final blood product.

35. One comment concerning proposed § 606.65(d)(3) (now incorporated into § 606.160(b)(5)(ii) and (b)(7)(vi)) interpreted the proposed paragraph as requiring that blood establishments repeat the tests performed by the manufacturer of the material. The comment indicated that most blood establishments do not have the equipment or expertise to retest purchased materials.

The Commissioner advises that the comment incorrectly interpreted the requirement. The regulation does not require that the blood establishment repeat the test performed by the manufacturer of the material. Rather, the intent of the regulation is to require a record of performance checks of equipment and reagents as prescribed in § 606.160(b)(5)(ii) of the final regulations.

36. The requirements in proposed § 606.65(e) concerning testing of reagents for potency and the maintenance of records have been transferred to §§ 606.65(c) and 606.160(b)(7)(i), respectively. The paragraphs in § 606.65 have been renumbered accordingly.

37. Eight comments concerning proposed § 606.65(f) (redesignated § 606.65(d)) generally agreed with the principle of storing the material in such a manner that the oldest is used first. However, four comments suggested that the requirement should not apply to reagents or supplies bearing an expiration date, as long as these materials are used within the dating period. Additionally, four comments questioned the need to promulgate such a requirement.

The Commissioner agrees that there is no need to require that products bearing a dating period be used on an "oldest-first" basis, in that these products have been tested and shown to maintain adequate potency and effectiveness during the entire length of the dating period. Consequently, there is no objection to using such products any time within the dating period. However, labels do not generally indicate the rate of loss of potency and effectiveness of products not bearing a dating period. To assure no loss of potency or effectiveness, these materials should be used on a first-in-first-out basis. Accordingly, § 606.65(d) has been amended to apply to products that do not bear an expiration date.

38. One comment concerning proposed § 606.65(h) (redesignated § 606.65(f)) re-

quested that the word "possible" be changed to "practical."

The Commissioner believes that disposability is an effective means of reducing the spread of infectious disease, especially the spread of hepatitis B virus. The accrued benefits of using disposables override all other considerations of practicality. Accordingly, the comment is rejected and no change is made in the regulations.

#### STANDARD OPERATING PROCEDURES

39. It has come to the attention of the Commissioner that § 606.100(a), as proposed, could be misinterpreted as requiring that establishments not subject to licensure must comply with those specific provisions in Part 640 (21 CFR Part 640) which, by their terms, apply only to licensed establishments. Accordingly, proposed § 606.100(a) is amended in the final regulation to provide that the references in Part 640 relating to licenses, licensed establishments and submission to and approval by the Director, Bureau of Biologics, are not applicable to non-licensed establishments.

Of course, the standard operating procedures that unlicensed establishments are required by these regulations to follow must comply with the substantive procedures for specific blood products set forth in Part 640.

40. One comment concerning proposed § 606.100(b) objected to the requirement that blood establishments maintain written standard operating procedures. The comment suggested that the art of blood banking may be downgraded if all steps were required to be written.

The Commissioner disagrees with this comment. The manual is intended to describe the best techniques, procedures and policies developed by blood banking practitioners. The Commissioner believes that the guidance provided to personnel from use of the manual, together with personnel development concerning attentiveness to detail, experience, training, common sense, etc., can only upgrade the art of blood banking.

41. Another comment concerning proposed § 606.100(b) requested guidance for the collection of blood intended for autologous transfusion, a transfusion in which the patient is infused with his own blood that was withdrawn on a previous occasion.

The Commissioner will issue at another time proposed additional standards governing products intended for autologous transfusion. In the meantime, any facility that collects blood for autologous transfusion must describe in the Standard Operating Procedures Manual, the steps followed from collection to distribution of such units. The manual of each licensed blood establishment is reviewed by the Bureau of Biologics at the time of licensure to assure that all procedures described therein are safe and result in a product that is safe, pure, potent and effective. Manuals of unlicensed establishments are subject to review during inspection by the FDA, but need not be submitted to the Bureau of Biologics for approval. To promote specificity and

clarity of the regulation, the Commissioner has amended § 606.100(b) by identifying homologous transfusion, autologous transfusion, and further manufacture of blood and blood components as procedures that must be described in the written Standard Operating Procedures Manual.

42. Three comments concerned proposed § 606.100(b)(5). Two of these comments objected to weighing each unit of blood on the basis that it is costly and unnecessary. The comments suggested that quality control of equipment will assure collection of blood within an acceptable range. The third comment suggested that the regulation be amended to provide a recommendation concerning the equipment to be used for weighing.

The Commissioner believes that the comments misinterpreted the regulation. The intent of the regulation is to ensure that the quantity of blood taken from the donor does not exceed the volume permitted by regulation. This is normally accomplished by the use of an in-process device which, based upon weight, mass or volume, signals the completion of the donation. Indeed, the regulation does not anticipate the weighing of each unit of blood when the in-process device has been demonstrated to be accurate and reliable. Rather, the regulation anticipates written procedures concerning use and maintenance of the device to assure its accuracy and reliability. Finally, the Commissioner concludes that there is no need to recommend specific equipment to be used for measuring the quantity of blood removed from the donor. The specific equipment used by the blood establishment should be described in the written Standard Operating Procedures Manual and will be reviewed during inspection by the FDA. Accordingly, no change is made in § 606.100(b)(5).

43. Two comments concerning proposed § 606.100(b)(7) noted that after publication of this proposal, a notice was published in the *FEDERAL REGISTER* of July 9, 1974 (39 FR 25233) proposing to amend § 610.40 *Tests for hepatitis B surface antigen* (21 CFR 610.40) to require testing of blood for hepatitis B surface antigen by a method of third generation sensitivity. The comments recommended that the requirement to use a method of third generation sensitivity be reflected in § 606.100(b)(7).

The Commissioner accepts the comments and § 606.100(b)(7) has been amended accordingly.

44. The Commissioner has added a new paragraph (b)(9) to proposed § 606.100 concerning procedures for investigating adverse reactions. The proposed paragraph (b)(9) and those following are renumbered accordingly. The reason for adding the new paragraph is that proposed § 606.170 *Adverse reaction file* requires that a thorough investigation be made for each reported adverse reaction. The Commissioner concludes that the procedures for carrying out the investigation should be described in the Standard Operating Procedures Manual to provide guidance to personnel involved in the investigation.



45. Two comments concerning proposed § 606.100(b)(10) (redesignated § 606.100(b)(11)) indicated that the requirement to identify the length of expiration dates assigned for all final products may cause confusion since some products such as Source Plasma (Human) and Recovered Plasma (Human), do not have expiration dates.

The Commissioner accepts the comments. Accordingly, to clarify the regulation, the phrase "if any" is added after the phrase "Length of expiration date" in § 606.100(b)(11).

46. The Commissioner has added a new paragraph (b)(18) to proposed § 606.100 concerning procedures for preparing recovered (salvaged) plasma. The paragraph is added in response to a number of general comments requesting greater specificity in the regulations.

47. Six comments objected to proposed § 606.100(c), which they interpreted as requiring a single comprehensive review of all applicable records at the time of distribution of blood or blood components. Another comment indicated that the paragraph seemed to be directed toward blood products rather than fresh blood or fresh blood components.

The Commissioner concludes that the comments have misinterpreted the intent of the regulation. The regulation requires that the records pertaining to a product be reviewed prior to distributing the product, not necessarily immediately prior to distribution. The review, or portions of the review, may be conducted at appropriate periods during or after blood collecting, processing, compatibility testing and storing. Additionally, the regulation is intended to apply to establishments preparing any blood product, including fresh blood and fresh blood components. Accordingly, the Commissioner has amended § 606.100(c) to clarify the intent.

#### PLATELETPHERESIS, LEUKAPHERESIS AND PLASMAPHERESIS

48. Twenty-five comments concerned proposed § 606.110 *Plasmapheresis*. Most of the comments were substantively the same as, or similar to, comments received in response to a notice published in the *FEDERAL REGISTER* of July 17, 1974 (39 FR 26161) proposing to expand the definition of Source Plasma (Human) in Part 640 to include all products collected by plasmapheresis, except Single Donor Plasma (Human) intended for intravenous use. The final regulations responsive to the July 17, 1974 proposal will prescribe requirements for Source Plasma (Human) intended for preparation of components for injection or for further manufacture into noninjectable products.

The Commissioner has determined that these good manufacturing practice regulations no longer need to prescribe specific requirements for plasmapheresis since proposed § 606.100 requires that the standard operating procedures must comply with the regulations for Source Plasma (Human) as presently drafted and as they may be amended. For continuity in the discussion relating to

plasmapheresis, the Commissioner will respond to the comments concerning plasmapheresis and proposed § 606.110 in the preamble to the final regulations concerning Source Plasma (Human) which will be published in the near future.

The Commissioner recognizes that in the meantime, provision should be made to permit the plasmapheresis of a donor who does not meet the requirements of §§ 640.63, 640.64 and 640.65 for the collection of plasma containing rare antibodies. Accordingly, the Commissioner has added a new paragraph (b) to § 606.110 to permit such plasmapheresis of a donor only with approval of the Director, Bureau of Biologics.

49. Two comments concerning proposed § 606.110 noted that neither the proposed regulation nor any of the existing biologic regulations prescribe the use of leukapheresis and plateletpheresis procedures for obtaining leukocytes or platelets, respectively, from a donor. The comments expressed concern that these procedures would no longer be permitted when needed for specific patients requiring repeated leukocyte or platelet transfusions.

The Commissioner advises that use of plateletpheresis as a source of Platelet Concentrate (Human) was provided for in the Additional Standards for Platelet Concentrate (Human), §§ 640.20 through 640.26 published in the *FEDERAL REGISTER* of January 29, 1975 (40 FR 4300). The use of the leukapheresis procedure, as indicated by the comment, is not presently prescribed by the existing biologic regulations.

The provisions prescribed in §§ 640.21(c) and 640.22(c) (21 CFR 640.21(c) and 640.22(c)) of the Additional Standards for Platelet Concentrate (Human) require that when plateletpheresis is used, the criteria of donor suitability and collection procedure must have written approval of the Director, Bureau of Biologics. Such approval is granted only after the blood establishment has demonstrated that the criteria and procedures will assure safety of the donors. These provisions, however, may preclude the use of plateletpheresis by a hospital in emergency situations when a physician has determined that the recipient must be transfused with the platelets from a specific donor, but the donor does not meet the criteria of weight, blood pressure, etc., approved by the Bureau of Biologics in accordance with § 640.21(c).

The Commissioner recognizes that leukapheresis and plateletpheresis are important to a hospital for collecting large volumes of leukocytes and platelets, especially from a small number of donors who are selected because of the compatibility of their blood with that of the recipient. Indeed, the most medically desirable donors are often relatives of the recipient.

Leukapheresis and plateletpheresis involve the return of nearly all the plasma, plus the formed elements, minus the leukocytes or platelets, respectively. These procedures do not significantly reduce the oxygen-carrying, oncotic or volu-

metric capacities of the donor's circulating system. Therefore, use of these procedures presents no long-term risks that could not be assessed by a physician at the time of donation. The Commissioner believes that provision must be made in the regulations to permit use of these life-saving procedures.

Accordingly, proposed § 606.110 has been amended to permit the use of the leukapheresis and plateletpheresis procedures when (a) the physician has determined that the recipient must be transfused with the leukocytes or platelets from a specific donor; (b) the procedure is performed under the supervision of a physician who is aware of the health status of the donor; and (c) the physician has certified in writing that the donor's health permits leukapheresis or plateletpheresis. Under such circumstances, the requirements prescribed in §§ 640.21(c) and 640.22(c) concerning prior approval of the criteria of donor suitability and the collection procedure of plateletpheresis by the Director, Bureau of Biologics, are waived. The Commissioner believes that such emergency provisions for plateletpheresis also should be reflected in the regulations governing the manufacture of Platelet Concentrate (Human). Accordingly, a new § 640.27 *Emergency provisions* is added to Platelet Concentrate (Human) regulations.

#### LABELING

50. One comment concerning proposed § 606.120(a)(1) suggested that the regulation be amended to permit a multilocation establishment to proof all labeling at one location. The comment interpreted the regulation as requiring that each location must proof the label against an approved final copy.

The Commissioner advises that the regulation was misinterpreted. The regulation does not prohibit a multilocation establishment from reviewing and proofing all labels at one location. Accordingly, no change is made in the regulation.

51. Two comments concerned proposed § 606.120(b). One comment recommended that the regulation be revised to require that labels applied by one blood service not be altered in any way by another blood service. The other comment recommended that the regulation be revised to permit a hospital to replace the original label, since the original label may be confusing to a physician who administers the product.

The Commissioner advises that the label information provided by the collection facility and the initial processing facility are necessary to identify and confirm that the product is safe, pure, potent and effective, and to facilitate the tracing of a product back to its original source. Indeed, the Commissioner did not anticipate that the regulation might be interpreted to imply that the original label may be removed, altered or obscured. Accordingly, to prevent any misinterpretation of the regulation, a sentence has been added to § 606.120(b) to prohibit any alteration of the original label. However, this does not preclude a hospital from adding further informa-



tion to a product container, provided the original label is not removed, altered or obscured. Accordingly, the Commissioner rejects the comment concerning replacement of the original label.

The Commissioner recognizes that under certain circumstances in the manufacture of blood components, the original label of the source material must be altered to provide accurate identification of the proper name of the product. For example, after plasma is removed from Whole Blood (Human), the remaining product is Red Blood Cells (Human). Accordingly, § 606.120(b) is amended in the final regulation to permit altering of labels, as necessary, to reflect the proper name of the product and other required labeling information for the contents remaining in a container after blood components have been removed.

52. One comment concerning proposed § 606.120(b) (5) suggested that the necessary instructions and precautions for use be required for the directions circular only and not on the product label.

The Commissioner concludes that the requirement as proposed is consistent with §§ 610.60 and 610.61 (21 CFR 610.60 and 610.61) prescribing the information that must appear on the container and package labels of all biological products. Accordingly, the comment is rejected. However, the Commissioner recognizes that certain information, such as the formula of the anticoagulant solution in the container, need be contained only in an instruction circular. For this reason, the Commissioner is reviewing the present labeling requirement for all blood products with the intent of publishing a proposal in the near future concerning a revised uniform labeling requirement.

53. Two comments concerning proposed § 606.120(b) (7) recommended that distribution of instruction circulars for whole blood and blood components not be required. Another comment suggested that the instruction circular not necessarily accompany each unit of blood.

The Commissioner recognizes that those experienced in performing transfusions may not need to refer to the instruction circular each time a transfusion is given. However, the circular provides a valuable synopsis of the best available information on the uses, precautions and contraindications associated with the use of blood and blood components. This information may be utilized by interns and residents, as well as recently transfused patients. Moreover, labeling for these drug products must, pursuant to section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f) (1)), bear adequate directions for lay use. Accordingly, the Commissioner rejects the comments recommending that distribution of the instruction circular not be required. The Commissioner did not intend, nor does the regulation imply, that the circular accompany each unit of whole blood. Rather, the regulation requires that circulars must be available in the collecting and transfusing facilities for reference, as needed, by transfusionists, interns, residents and patients.

54. Two comments concerning proposed § 606.120(b) (8) requested that a provision be added to permit the volume of a product in a container to vary by  $\pm 10$  percent from the volume stated on the label. Another comment noted that the quantity of product is normally not specified for certain products, e.g., Cryoprecipitated Antihemophilic Factor (Human).

The Commissioner acknowledges that certain measurement devices presently used by blood banks are accurate only within a 10 percent range. Consequently a unit of whole blood is recognized as being within  $\pm 10$  percent of the volume stated on the label. Since a discrepancy of  $\pm 10$  percent of the volume stated on the label does not affect the safety, purity, potency and effectiveness of the product, the Commissioner has amended the regulation to permit the quantity of product stated on the label to be accurate to within  $\pm 10$  percent. However, it should be emphasized that the amendment does not affect, in any manner, the maximum amount of whole blood, which by regulation is permitted to be removed from a donor, i.e., § 640.65(b) (4), (5) and (6) (21 CFR 640.65(b) (4), (5) and (6)). The Commissioner recognizes that it is impractical to determine the volume of Cryoprecipitated Antihemophilic Factor (Human) in a container, and proposed § 606.120(b) (8) is not intended to apply to this product. Rather, proposed paragraph (b) (9) is applicable and consistent with § 640.51(c) (6) (21 CFR 640.51(c) (6)) concerning Cryoprecipitated Antihemophilic Factor (Human), requiring that the quantity of source plasma, and kind and quantity of anticoagulant appear on the labeling. Accordingly, to ensure that there is no misinterpretation concerning the intent of proposed paragraph (b) (8), the Commissioner has added a phrase exempting this product from the requirement that the labeling indicate the quantity of product in the container and further providing that the  $\pm 10$  percent variance does not apply to Source Plasma (Human) for which precise weight measurement is regularly attained.

#### LABORATORY CONTROLS

55. Two comments concerning proposed § 606.140 requested that the regulation be revised to specifically define requirements such as "adequate" monitoring, "appropriate" specifications, and the like.

The Commissioner believes that each blood establishment should select its own specific laboratory control procedures applicable to the processes it performs, its equipment, personnel and other variable factors. The regulations are intended as a general guideline for use by a blood establishment in developing specific laboratory control procedures. There are available recognized laboratory control guides, such as Quality Control in Blood Banking, American Association of Blood Banks, 1973, or Myhre, B.A. and Quality Control in Blood Banking, Wiley and Sons Inc., NY 1974, which provide pro-

cedures for implementing the standards set forth in these regulations. Accordingly, the comments are rejected.

#### COMPATIBILITY TESTING

56. Two comments concerning proposed § 606.151 argued that crossmatching is not, and should not, be within the province of the FDA, inasmuch as it is a procedure performed entirely within the hospital laboratory.

The Commissioner advises that in some instances community blood banks perform crossmatching procedures in place of the hospital laboratory. In addition, the Commissioner believes that his authority under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to regulate all aspects of blood and blood components processing and testing has been adequately documented in the preamble of the proposal. The Commissioner considers the crossmatching, as well as other compatibility tests to be as significant to blood as the general safety test described in § 610.11 (21 CFR 610.11) is to other biological products. Indeed, it is impossible for the Commissioner to assure the safety, purity, potency and effectiveness of blood and blood products without the authority to assure that all compatibility tests are accurate and reliable.

57. Two comments concerning the introductory paragraph of proposed § 606.151 requested that the first sentence be deleted. The comments indicated that it is unreasonable for a small institution to require an entirely separate area for compatibility testing.

The Commissioner accepts the comments. It is not essential that an area be set aside for compatibility tests only. Rather, it is essential that compatibility testing be conducted in a work area that is arranged in an orderly manner so as to avoid mixups or contamination of the product. This requirement is already addressed in proposed § 606.40(a) (7). Accordingly, the Commissioner has deleted the first sentence from the introductory paragraph of § 606.151.

58. Three comments concerning proposed § 606.151(b) objected to the requirement that serum be less than 48 hours old for all compatibility testing. The comments suggested that there is adequate data in the literature to support use of serum older than 48 hours for such testing. Also, one comment suggested that the serum for compatibility testing should be less than 6 hours old.

The Commissioner prescribed the 48-hour limit on the basis of data demonstrating that antibodies in a blood recipient's serum 48 hours old can adequately be detected by compatibility testing. Accordingly, the Commissioner rejects the comment suggesting that serum be less than 6 hours old. Serum samples stored at refrigerator temperatures beyond 48 hours may become contaminated with airborne microorganisms. Some microorganisms produce substances capable of agglutinating red cells and may, therefore, predispose serum to false positive agglutination reactions. Accordingly,



the Commissioner rejects the comment and no change is made in the regulations. However, the FDA is conducting a review of available data concerning compatibility testing with serum that is 72 hours old. Interested persons are encouraged to send such data, or references to such data, to the Director, Bureau of Biologics, 8800 Rockville Pike, Bethesda, MD 20014. The Commissioner will propose to extend the 48-hour limit to 72 hours or longer if available data support such extension.

59. Five comments concerning paragraph (c) and (d) of proposed § 606.151 suggested that the major crossmatch test include testing for hemolytic antibodies, as well as the already required agglutinating and coating antibodies.

The Commissioner intends that the major crossmatch test include testing for all antibodies of major concern. Hemolytic antibodies are of major concern but were inadvertently omitted in the proposed regulation. Accordingly, the Commissioner accepts the comments and paragraphs (c) and (d) have been amended as suggested by the comments.

60. One comment concerning proposed § 606.151(d) requested that provision be made to permit screening of the donor's blood by any method that has been demonstrated to be at least equivalent to the antiglobulin method for determining the presence of agglutinating, coating and hemolytic antibodies. Included with the comment was data supporting use of an enzyme method proposed for use in place of the antiglobulin method.

The Commissioner believes that the regulation should anticipate the use of other methods that are equivalent to, or better than, the antiglobulin method for demonstrating antibodies in the donor's blood. Additionally, the Commissioner concludes that the data submitted with the comment demonstrate that the enzyme method is at least equivalent to the antiglobulin method. Accordingly, § 606.151(d) has been revised in the final regulation to permit screening of a donor's blood by any method that will demonstrate agglutinating, coating and hemolytic antibodies.

61. Two comments concerning proposed § 606.151(d) suggested that the minor crossmatch test be required whether or not donor screening is performed. The comments indicated that the test is important as an additional check to assure that the patient is given the proper blood. Another comment suggested that reference to the minor crossmatch be deleted and replaced with a requirement that all donor sera be tested by methods adequate to detect clinically significant antibodies. The comment stated that there are good reasons for the undesirability of performing the minor crossmatch and also inter se crossmatches. However, the specific reasons were not given.

As evidenced by the comments, there is disagreement within the scientific community concerning the advantages of the screening test versus the minor crossmatch test and the practical need to perform one of these tests if the other al-

ready has been performed. In light of this disagreement, and since the available data equally support advantages of either test procedure, the Commissioner, in the proposed regulation, has permitted use of the screening test or the minor crossmatch test as alternative testing procedures. No new data demonstrating that one testing procedure is superior to the other has been made available to the Commissioner. For these reasons, the Commissioner rejects the comment requesting that reference to the minor crossmatch test be deleted. The Commissioner believes that the major crossmatch test required by paragraph (c), together with a test designed either to screen the donor's serum or to reflect compatibility of the donor's serum with the recipient's red blood cells (minor crossmatch), are practical, necessary and adequate to protect the recipient from a transfusion with incompatible blood. Accordingly, the Commissioner also rejects the comment requesting that both screening and minor crossmatch tests be required prior to transfusion, and no change is made in the regulation.

62. Seven comments concerning proposed § 606.151(e) objected to the words "modified" and "safe" to describe the procedures for expedited transfusions in emergencies. The comments noted that in an emergency situation there is normally not enough time to conduct all required testing of the blood. Consequently, the blood cannot be determined to be as safe as blood processed under normal conditions.

The Commissioner recognizes the limited assurances provided by any emergency procedure and therefore accepts the comments, and the words "modified" and "safe" have been deleted from § 606.151(e) of the final regulation. The Commissioner notes that the comments interpreted the word "procedures" as strictly applying to the method of performing the crossmatch. However, it should be emphasized that the term "procedure" includes administrative procedures relating to emergency transfusions as well as the technical procedures.

#### RECORDS

63. Three comments concerning proposed § 606.160(a) (redesignated as § 606.160(a)(1)) requested clarification of the significant steps for which records must be maintained and questioned the need for maintaining certain records, especially those that identify the person performing the work.

The Commissioner has used the term "significant step" to mean any step that may affect the safety of the donor and recipient, or the safety, purity, potency and effectiveness of the product. For example, with respect to blood collection, the amenities provided the donor prior to the interview or following blood donation are not significant steps requiring the maintenance of records. However, any aspect of the donor interview concerning his suitability and the phlebotomy is a significant step requiring the maintenance of records, signed or initialed by person(s) who actually per-

formed the work. The Commissioner recognizes that supervisors may have ultimate responsibility for the performance of their staff. Nevertheless, employees having direct responsibility for any significant step may need to be identified if deficiencies and substandard practices are to be expeditiously corrected. Accordingly, the Commissioner accepts the comments requesting clarification of significant steps and a new proposed § 606.160(b) has been added to the regulation to specifically identify the records that must be maintained.

64. Several comments requested guidance concerning recordkeeping methods and requirements generally. In conjunction with this section of the regulation, the Commissioner will publish a proposal concerning the tabulation of recorded data in order to promote meaningful review and monitoring by the blood establishment and to facilitate a scheduled annual survey of all blood establishments by FDA.

65. Five comments concerning proposed § 606.160(c) (redesignated as § 606.160(d)) indicated that it is unrealistic to require that records of processing Source Plasma (Human) be retained for 6 months after the expiration date of the final product manufactured from the Source Plasma (Human). The comments noted that Source Plasma (Human) is normally sold to another establishment for further manufacture. Consequently, the Source Plasma (Human) supplier has no way of knowing the latest expiration date of the final product. One comment suggested it would be more practical to require that the supplier retain the records indefinitely, while two other comments suggested 5 years.

The Commissioner recognizes that it may be impractical, or perhaps impossible, for the supplier of Source Plasma (Human) to know the latest expiration date of a final product processed by another establishment. Consequently, it is also impractical to require that the supplier retain records of processing for 6 months after the latest expiration date for the final product that was manufactured from the source plasma. For this reason, the Commissioner intends to publish, at another time, a notice of proposed rule making to prescribe an expiration date for Source Plasma (Human). Interested persons will be given an opportunity for comment. The Commissioner has determined that in the interim, records of products having no expiration dates shall be retained indefinitely to facilitate the reporting of any unfavorable clinical reactions. Accordingly, § 606.160 has been amended in paragraph (e) to require that records be retained indefinitely when the product has no expiration date.

66. Three comments concerning proposed § 606.160(d) (redesignated § 606.160(e)) asked whether the regulation required that establishments maintain a separate list of unsuitable donors or permitted the flagging of individual donor records. One comment further asked whether the record of unsuitable donors must include the names of donors who are only temporarily unsuitable. Another



comment indicated that it is impractical to carry a complete list of unsuitable donors on mobile operations.

The Commissioner intended that the major impact of the regulation was to preclude from the marketplace, blood or blood products obtained from an unsuitable donor. The Commissioner advises that each blood establishment may develop its own system of recordkeeping to effectively identify unsuitable donors. Accordingly, the regulation does not prescribe a special system of recordkeeping. Rather, any record system used by a blood establishment must facilitate the identification of an unsuitable donor. The Commissioner agrees that it may be impractical, on a mobile operation, to carry a complete list of unsuitable donors. Therefore, upon return of the mobile unit to the blood establishment, donor records must be reviewed and action taken to assure that blood collected from an unsuitable donor will not be distributed. Accordingly, the Commissioner has amended the regulation to emphasize that records must be available so that products from unsuitable donors will not be distributed.

#### DISTRIBUTION AND RECEIPT; PROCEDURES AND RECORDS

67. One comment concerning proposed § 606.165 argued that unnecessary paperwork would be required if every unit of blood issued by a central blood bank must contain the name and address of the hospital. Another comment suggested that there is little need to specify on each distribution record the address of a consignee who is frequently supplied with the product. The comment suggested that the addresses of such consignees are always easily available at the blood establishment.

The Commissioner advises that the regulation does not require each unit of blood to have on its container the name and address of the hospital to which the unit is being sent. Rather, it requires that such information be in the distribution record of the blood establishment shipping the blood. The Commissioner agrees with the comment that the address of a consignee on each distribution record may not be needed if such information is easily available elsewhere in the blood establishment records in a form that will readily facilitate recall of a product. Accordingly, the regulation has been amended to require that distribution records contain information to facilitate the rapid identification of the name and address of the consignee.

68. In the original notice, the Commissioner proposed to require the maintenance of records for "each significant step" in the manufacture of blood products. It was the Commissioner's intent that records of receipt of blood and blood components be included since a system of recordkeeping of such data is essential to assure the identity and permit recall, if necessary, of each unit of blood. Indeed, almost all establishments receiving blood products recognize the importance of maintaining such records and currently do so. The Commissioner has con-

cluded that to promote specificity, the regulation should explicitly require such a system of recordkeeping and that such requirement be set forth in the new § 606.165 along with similar requirements applicable to distribution. Accordingly, that section has been amended to include requirements for receipt of blood and blood components in order to facilitate recall of blood products. In order to clarify any possible misapprehension that may have occurred concerning the scope of the proposal regarding records for receipt, the Commissioner will consider additional comments concerning this aspect of the regulation within the next 30 days, and such comments may justify further modification of this provision.

#### ADVERSE REACTION FILE

69. Twenty-three comments concerned proposed § 606.170 dealing with adverse reaction files. The comments posed general questions concerning the intended objectives of the proposed regulation. Almost all comments requested that the term "severe adverse reaction" be defined.

The Commissioner advises that the objective of the regulation is to reduce the possibility of adverse reactions by (a) determining the cause of the reaction; and (b) providing safeguards that eliminate, where possible, the causes leading to an adverse reaction. To achieve this objective, the technical staff of each transfusion facility must be informed of all transfusion reactions so that data may be made available to a physician to confirm suspected causes, including sequelae, such as antibody development that might require further blood usage demanding special technical handling, and to review and evaluate the adequacy of laboratory methods. For these reasons, transfusion reactions must be reported to the laboratory and records maintained there, in addition to any notes that may be inserted in the patient's chart. Additionally, the collecting facility must be informed of all transfusion reactions when the reaction is attributed to a defect in the product obtained from the collecting facility. Accordingly, the regulation has been revised in § 606.170 to require clearly that (a) records be kept concerning any adverse reaction to the donor or recipient, (b) reports of each reaction be investigated, (c) transfusion reaction reports be communicated to and retained by the collecting facility when the reaction is attributed to a defect in the product, and (d) the Director, Bureau of Biologics, be informed of any deaths implicating a blood donation or transfusion as the cause.

The Commissioner uses the term "severe adverse reaction" to mean a fatal reaction. The Director, Bureau of Biologics, must be notified by telephone or telegraph as soon as possible when a blood donation or transfusion has been found to cause death, and a written report of the investigation must be submitted to the Director, Bureau of Biologics, within 7 days after the fatality.

Under the Administrative Procedure Act (5 U.S.C. 533(b) and (d)), the Commissioner concludes that notice, public procedure and delayed effective date are unnecessary for the promulgation of § 640.27 as it does not impose an additional duty or burden on any person but rather relieves a restriction concerning plateletpheresis consistent with these good manufacturing practice regulations. Comments are nevertheless requested within the next 30 days and may justify further modification of this provision.

Therefore, under provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 510, 701, 52 Stat. 1040-1042 as amended, 1049-1050 as amended by 76 Stat. 780, 1055-1056 as amended, 76 Stat. 794 as amended, and sec. 301 of Pub. L. 87-781 (21 U.S.C. 321, 351, 352, 360 and note, 371)), the Public Health Service Act (secs. 351 and 361, 58 Stat. 702 and 703 as amended (42 U.S.C. 262 and 264)), and the Administrative Procedure Act (secs. 4 and 10, 60 Stat. 238 and 243, as amended (5 U.S.C. 553, 702, 703, 704)) and under authority delegated to the Commissioner (21 CFR 2.120), Chapter I of Title 21 of the Code of Federal Regulations is amended in Subchapter F as follows:

1. By adding a new Part 606 to read as follows:

Subpart A—General Provisions	
Sec. 606.3	Definitions.
Subpart B—Organization and Personnel	
606.20	Personnel.
Subpart C—Plant and Facilities	
606.40	Facilities.
Subpart D—Equipment	
606.60	Equipment.
606.65	Supplies and reagents.
Subpart E—[Reserved]	
Subpart F—Production and Process Controls	
606.100	Standard operating procedures.
606.110	Plateletpheresis, leukapheresis and plasmapheresis.
Subpart G—Finished Product Control	
606.120	Labeling.
Subpart H—Laboratory Controls	
606.140	Laboratory controls.
606.151	Compatibility testing.
Subpart I—Records and Reports	
606.160	Records.
606.165	Distribution and receipt; procedures and records.
606.170	Adverse reaction file.

AUTHORITY: Secs. 201, 501, 502, 510, 701, 52 Stat. 1040-1042 as amended, 1049-1051 as amended by 76 Stat. 780, 1055-1056 as amended, 76 Stat. 794 as amended, and sec. 301 of Pub. L. 87-781 (21 U.S.C. 321, 351, 352, 360 and note, 371)), the Public Health Service Act (secs. 351 and 361, 58 Stat. 702 and 703 as amended (42 U.S.C. 262 and 264)), and the Administrative Procedure Act (secs. 4 and 10, 60 Stat. 238 and 243, as amended (5 U.S.C. 553, 702, 703, 704)).

#### Subpart A—General Provisions

##### § 606.3 Definitions.

As used in this part:

(a) "Blood" means whole blood collected from a single donor and processed



either for transfusion or further manufacturing.

(b) "Unit" means the volume of blood or one of its components in a suitable volume of anticoagulant obtained from a single collection of blood from one donor.

(c) "Component" means that part of a single-donor unit of blood separated by physical or mechanical means.

(d) "Plasma for further manufacturing" means that liquid portion of blood separated and used as material to prepare another product.

(e) "Plasmapheresis" means the procedure in which blood is removed from the donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the donor. This process may be immediately repeated, once.

(f) "Plateletpheresis" means the procedure in which blood is removed from the donor, a platelet concentrate is separated, and the remaining formed elements and residual plasma are returned to the donor.

(g) "Leukapheresis" means the procedure in which blood is removed from the donor, a leukocyte concentrate is separated, and the remaining formed elements and residual plasma are returned to the donor.

(h) "Facilities" means any area used for the collection, processing, compatibility testing, storage or distribution of blood and blood components.

(i) "Processing" means any procedure employed after collection and before compatibility testing of blood and includes the identification of a unit of donor blood, the preparation of components from such unit of donor blood, serological testing, labeling and associated recordkeeping.

(j) "Compatibility testing" means the in vitro serological tests performed on donor and recipient blood samples to establish the serological matching of a donor's blood or blood components with that of a potential recipient.

#### Subpart B—Organization and Personnel

##### § 606.20 Personnel.

(a) A blood establishment shall be under the direction of a designated, qualified person who shall exercise control of the establishment in all matters relating to compliance with the provisions of this subchapter. This person shall also have the authority to represent the establishment in all pertinent matters with the Bureau of Biologics and to enforce, or direct the enforcement of, discipline and the performance of assigned functions by employees engaged in the collection, processing, compatibility testing, storage and distribution of blood and blood components. The designated director shall have an understanding of the scientific principles and techniques involved in the manufacture of blood products and shall have the responsibility for ensuring that employees are adequately trained in standard op-

erating procedures and that they are aware of the application of the pertinent provisions of this chapter to their respective functions.

(b) The personnel responsible for the collection, processing, compatibility testing, storage or distribution of blood or blood components shall be adequate in number, educational background, training and experience, including professional training as necessary, or combination thereof, to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the procedures or control operations they perform, the necessary training or experience, and adequate information concerning the application of pertinent provisions of this part to their respective functions.

(c) Persons whose presence can adversely affect the safety and purity of the products shall be excluded from areas where the collection, processing, compatibility testing, storage or distribution of blood or blood components is conducted.

#### Subpart C—Plant and Facilities

##### § 606.40 Facilities.

Facilities shall be maintained in a clean and orderly manner, and shall be of suitable size, construction and location to facilitate adequate cleaning, maintenance and proper operations. The facilities shall:

(a) Provide adequate space for the following when applicable:

(1) Private and accurate examinations of individuals to determine their suitability as blood donors.

(2) The withdrawal of blood from donors with minimal risk of contamination, or exposure to activities and equipment unrelated to blood collection.

(3) The storage of blood or blood components pending completion of tests.

(4) The quarantine storage of blood or blood components in a designated location pending repetition of those tests that initially gave questionable serological results.

(5) The storage of finished products prior to distribution.

(6) The quarantine storage, handling and disposition of products and reagents not suitable for use.

(7) The orderly collection, processing, compatibility testing, storage and distribution of blood and blood components to prevent contamination.

(8) The adequate and proper performance of all steps in plasma-pheresis, plateletpheresis and leukapheresis procedures.

(9) The orderly conduction of all packaging, labeling and other finishing operations.

(b) Provide adequate lighting, ventilation and screening of open windows and doors.

(c) Provide adequate, clean, and convenient handwashing facilities for personnel, and adequate, clean, and convenient toilet facilities for donors and personnel. Drains shall be of adequate size and, where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.

(d) Provide for safe and sanitary disposal for the following:

(1) Trash and items used during the collection, processing and compatibility testing of blood and blood components.

(2) Blood and blood components not suitable for use or distribution.

#### Subpart D—Equipment

##### § 606.60 Equipment.

(a) Equipment used in the collection, processing, compatibility testing, storage and distribution of blood and blood components shall be maintained in a clean and orderly manner and located so as to facilitate cleaning and maintenance. The equipment shall be observed, standardized and calibrated on a regularly scheduled basis as prescribed in the Standard Operating Procedures Manual and shall perform in the manner for which it was designed so as to assure compliance with the official requirements prescribed in this chapter for blood and blood products.

(b) Equipment that shall be observed, standardized and calibrated with at least the following frequency, include but are not limited to:

Equipment	Performance check	Frequency	Frequency of calibration
Temperature recorder	Compare against thermometer	Daily	As necessary.
Refrigerated centrifuge	Observe speed and temperature	Each day of use	Do.
Hematocrit centrifuge	Standardize with control preparation	do.	Do.
General lab centrifuge			Tachometer every 6 mo.
Automated blood-typing machine	Observe controls for correct results	Each day of use	
Hemoglobinometer	Standardize against cyanmethemoglobin standard	do.	
Refractometer	Standardize against distilled water	do.	
Blood container scale	Standardize against container of known weight	do.	As necessary.
Water bath	Observe temperature	do.	Do.
Rh view box	do.	do.	Do.
Autoclave	do.	do.	Do.
Serologic rotators	Observe controls for correct results	do.	Speed as necessary.
Laboratory thermometers			Before initial use.
Electronic thermometers			Monthly.
Vacuum blood agitator	Standardize against container of known mass or volume	Each day of use	As necessary.



(c) Equipment employed in the sterilization of materials used in blood collection or for disposition of contaminated products shall be designed, maintained and utilized to ensure the destruction of contaminating microorganisms. The effectiveness of the sterilization procedure shall be no less than that achieved by an attained temperature of 121.5° C (251° F) maintained for 20 minutes by saturated steam at a pressure of 15 atmospheres or by an attained temperature of 170° C (338° F) maintained for 2 hours with dry heat.

#### § 606.65 Supplies and reagents.

All supplies and reagents used in the collection, processing, compatibility testing, storage and distribution of blood and blood components shall be stored in a safe, sanitary and orderly manner.

(a) All surfaces coming in contact with blood and blood components intended for transfusion shall be sterile, pyrogen-free, and shall not interact with the product in such a manner as to have an adverse effect upon the safety, purity, potency or effectiveness of the product. All final containers and closures for blood and blood components not intended for transfusion shall be clean and free of surface solids and other contaminants.

(b) Each blood collecting container and its satellite container(s), if any, shall be examined visually for damage or evidence of contamination prior to its use and immediately after filling. Such examination shall include inspection for breakage of seals, when indicated, and abnormal discoloration. Where any defect is observed, the container shall not be used, or, if detected after filling, shall be properly discarded.

(c) Representative samples of each lot of the following reagents or solutions shall be tested on a regularly scheduled basis by methods described in the Standard Operating Procedures Manual to determine their capacity to perform as required:

Reagent or solution	Frequency of testing
Anti-human serum	Each day of use.
Blood grouping serums	Do.
Lectins	Do.
Antibody screening and reverse grouping cells	Do.
Hepatitis test reagents	Each run.
Syphilis serology reagents	Do.
Enzymes	Each day of use.

(d) Supplies and reagents that do not bear an expiration date shall be stored in such a manner that the oldest is used first.

(e) Supplies and reagents shall be used in a manner consistent with instructions provided by the manufacturer.

(f) Items that are required to be sterile and come into contact with blood should be disposable whenever possible.

#### Subpart E—[Reserved]

#### Subpart F—Production and Process Controls

#### § 606.100 Standard operating procedures.

(a) In all instances, except clinical investigations, standard operating procedures shall comply with published additional standards in Part 640 of this chapter for the products being processed; except that, references in Part 640 relating to licenses, licensed establishments and submission of material or data to or approval by the Director, Bureau of Biologics, are not applicable to establishments not subject to licensure under section 351 of the Public Health Service Act.

(b) Written standard operating procedures shall be maintained and shall include all steps to be followed in the collection, processing, compatibility testing, storage and distribution of blood and blood components for homologous transfusion, autologous transfusion and further manufacturing purposes. Such procedures shall be available to the personnel for use in the areas where the procedures are performed, unless this is impractical. The written standard operating procedures shall include, but are not limited to, descriptions of the following, when applicable:

(1) Criteria used to determine donor suitability, including acceptable medical history criteria.

(2) Methods of performing donor qualifying tests and measurements, including minimum and maximum values for a test or procedure when a factor in determining acceptability.

(3) Solutions and methods used to prepare the site of phlebotomy to give maximum assurance of a sterile container of blood.

(4) Method of accurately relating the product(s) to the donor.

(5) Blood collection procedure, including in-process precautions taken to measure accurately the quantity of blood removed from the donor.

(6) Methods of component preparation, including any time restrictions for specific steps in processing.

(7) All tests and repeat tests performed on blood and blood components during processing, including testing for hepatitis B surface antigen as prescribed in § 610.40 of this chapter.

(8) Pretransfusion testing, where applicable, including precautions to be taken to identify accurately the recipient blood samples and cross-matched donor units.

(9) Procedures for investigating adverse donor and recipient reactions.

(10) Storage temperatures and methods of controlling storage temperatures for all blood products and reagents as prescribed in §§ 600.15 and 610.53 of this chapter.

(11) Length of expiration dates, if any, assigned for all final products as prescribed in § 610.53 of this chapter.

(12) Criteria for determining whether returned blood is suitable for reissue.

(13) Procedures used for relating a unit of blood or blood component from the donor to its final disposition.

(14) Quality control procedures for supplies and reagents employed in blood collection, processing and pretransfusion testing.

(15) Schedules and procedures for equipment maintenance and calibration.

(16) Labeling procedures, including safeguards to avoid labeling mixups.

(17) Procedures of plasmapheresis, plateletpheresis, and leukapheresis, if performed, including precautions to be taken to ensure reinfusion of a donor's own cells.

(18) Procedure for preparing recovered (salvaged) plasma, if performed, including details of separation, pooling, labeling, storage and distribution.

(c) All records pertinent to the lot or unit maintained pursuant to these regulations shall be reviewed before the release or distribution of a lot or unit of final product. The review or portions of the review may be performed at appropriate periods during or after blood collecting, processing, compatibility testing and storing. A thorough investigation, including the conclusions and followup, of any unexplained discrepancy or the failure of a lot or unit to meet any of its specifications shall be made and recorded.

(d) In addition to the requirements of this subpart and in conformity with this section, any facility may utilize current standard operating procedures such as the manuals of the following organizations, as long as such specific procedures are consistent with, and at least as stringent as, the requirements contained in this part.

(1) American Association of Blood Banks.

(2) American National Red Cross.

(3) Other organizations or individual blood banks, subject to approval by the Director, Bureau of Biologics.

#### § 606.110 Plateletpheresis, leukapheresis, and plasmapheresis.

(a) The use of plateletpheresis and leukapheresis procedures to obtain a product for a specific recipient may be at variance with the additional standards for specific products prescribed in this part provided that: (1) A physician has determined that the recipient must be transfused with the leukocytes or platelets from a specific donor, and (2) the procedure is performed under the supervision of a qualified licensed physician who is aware of the health status of the donor, and the physician has certified in writing that the donor's health permits plateletpheresis of leukapheresis.

(b) Plasmapheresis of donors who do not meet the donor requirements of §§ 640.63, 640.64 and 640.65 of this chapter for the collection of plasma containing rare antibodies shall be permitted only with the prior approval of the Director, Bureau of Biologics.

#### Subpart G—Finished Product Control

#### § 606.120 Labeling.

Labeling operations shall be separated physically or spatially from other operations in a manner adequate to prevent mixups.

(a) The labeling operation shall include the following labeling controls:

(1) Labels shall be held upon receipt, pending review and proofing against an approved final copy, to assure accuracy regarding identity, content and conformity with the approved copy.

(2) Each type of label representing different products shall be stored and main-



tained in a manner to prevent mixups and stocks of obsolete labels shall be destroyed.

(3) All necessary checks in labeling procedures shall be utilized to prevent errors in translating test results to container labels.

(b) All labeling shall be clear and legible. The label provided by the collecting facility and the initial processing facility shall not be removed, altered or obscured, except that, the label may be altered to indicate the proper name and other required labeling information for the contents remaining in a container after blood components have been removed. The container label shall include the following information as well as other specialized information, as required in this part or in Part 640 of this chapter for specific products:

(1) The proper name of the product placed in a prominent position.

(2) The name and address of the manufacturer, and if licensed, the license number.

(3) The donor or lot number relating the unit to the donor.

(4) The expiration date, including the day and year, and if it is a factor, the hour, or in the case of plasma for further manufacture, the date of collection.

(5) Essential instructions or precautions for use, including a warning that the product may transmit the agent of hepatitis.

(6) Recommended storage temperature.

(7) Reference to an instruction circular that shall be available for distribution containing dosage information, adequate directions for use, route of administration, contraindications and other directions if product is not intended for further manufacturing.

(8) Quantity of product in container, which shall be accurate within  $\pm 10$  percent, except that the quantity of Cryo-precipitated Antihemophilic Factor (Human) need not be stated on the label and except that this provision shall not apply to Source Plasma (Human).

(9) Quantity of source material, and the kind and quantity of anticoagulant.

(10) Additives and cryoprotective agents added to the product that may still be present.

(11) Results of all tests performed when necessary for safe and effective use.

(12) The statement: "Caution: For Manufacturing Use Only", where applicable.

(13) The immunizing antigen used or the antibody present for products for further manufacturing, when applicable.

#### Subpart H—Laboratory Controls

##### § 606.140 Laboratory controls.

Laboratory control procedures shall include:

(a) The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

(b) Adequate provisions for monitoring the reliability, accuracy, precision

and performance of laboratory test procedures and instruments.

(c) Adequate identification and handling of all test samples so that they are accurately related to the specific unit of product being tested, or to its donor, or to the specific recipient, where applicable.

##### § 606.151 Compatibility testing.

Standard operating procedures for compatibility testing shall include the following:

(a) A method of collecting and identifying the blood samples of recipients to ensure positive identification.

(b) The use of fresh recipient serum samples less than 48 hours old for all pretransfusion testing.

(c) The testing of the donor's cells with the recipient's serum (major crossmatch) by a method that will demonstrate agglutinating, coating and hemolytic antibodies, which shall include the anti-globulin method.

(d) A provision that, if the unit of donor's blood has not been screened by a method that will demonstrate agglutinating, coating and hemolytic antibodies, the recipient's cells shall be tested with the donor's serum (minor crossmatch) by a method that will so demonstrate.

(e) Procedures to expedite transfusions in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by the physician requesting the procedure.

#### Subpart I—Records and Reports

##### § 606.160 Records.

(a) (1) Records shall be maintained concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced. All records shall be legible and indelible, and shall identify the person performing the work, include dates of the various entries, show test results as well as the interpretation of the results, show the expiration date assigned to specific products, and be as detailed as necessary to provide a complete history of the work performed.

(2) Appropriate records shall be available from which to determine lot numbers of supplies and reagents used for specific lots or units of the final product.

(b) Records shall be maintained that include, but are not limited to, the following when applicable:

(1) Donor records:

(i) Donor selection, including medical interview and examination and where applicable, informed consent.

(ii) Permanent and temporary deferrals for health reasons including reason(s) for deferral.

(iii) Donor adverse reaction complaints and reports, including results of all investigations and followup.

(iv) Therapeutic bleedings, including signed requests from attending physi-

cians, the donor's disease and disposition of units.

(v) Immunization, including informed consent, identification of the antigen, dosage and route of administration.

(vi) Blood collection, including identification of the phlebotomist.

(2) Processing records:

(i) Blood processing, including results and interpretation of all tests and retests.

(ii) Component preparation, including all relevant dates and times.

(iii) Separation and pooling of recovered plasma.

(iv) Centrifugation and pooling of source plasma.

(v) Labeling, including initials of person(s) responsible.

(3) Storage and distribution records:

(i) Distribution and disposition, as appropriate, of blood and blood products.

(ii) Visual inspection of whole blood and red blood cells during storage and immediately before distribution.

(iii) Storage temperature, including initialed temperature recorder charts.

(iv) Reissue, including records of proper temperature maintenance.

(v) Emergency release of blood, including signature of requesting physician obtained before or after release.

(4) Compatibility test records:

(i) Results of all compatibility tests, including crossmatching, testing of patient samples, antibody screening and identification.

(ii) Results of confirmatory testing.

(5) Quality control records:

(i) Calibration and standardization of equipment.

(ii) Performance checks of equipment and reagents.

(iii) Periodic check on sterile technique.

(iv) Periodic tests of capacity of shipping containers to maintain proper temperature in transit.

(v) Proficiency test results.

(6) Transfusion reaction reports and complaints, including records of investigations and followup.

(7) General records:

(i) Sterilization of supplies and reagents prepared within the facility, including date, time interval, temperature and mode.

(ii) Responsible personnel.

(iii) Errors and accidents.

(iv) Maintenance records for equipment and general physical plant.

(v) Supplies and reagents, including name of manufacturer or supplier, lot numbers, expiration date and date of receipt.

(vi) Disposition of rejected supplies and reagents used in the collection, processing and compatibility testing of blood and blood components.

(c) A donor number shall be assigned to each accepted donor, which relates the unit of blood collected to that donor, to his medical record, to any component or blood product from that donor's unit of blood, and to all records describing the history and ultimate disposition of these products.

(d) Records shall be retained for such interval beyond the expiration date for



the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. The retention period shall be no less than 5 years after the records of processing have been completed or 6 months after the latest expiration date for the individual product, whichever is a later date. When there is no expiration date, records shall be retained indefinitely.

(e) A record shall be available from which unsuitable donors may be identified so that products from such individuals will not be distributed.

**§ 606.165 Distribution and receipt; procedures and records.**

(a) Distribution and receipt procedures shall include a system by which the distribution or receipt of each unit can be readily determined to facilitate its recall, if necessary.

(b) Distribution records shall contain information to readily facilitate the identification of the name and address of the consignee, the date and quantity delivered, the lot number of the unit(s), the date of expiration or the date of collection, whichever is applicable, or for crossmatched blood and blood components, the name of the recipient.

(c) Receipt records shall contain the name and address of the collecting facility, date received, donor or lot number assigned by the collecting facility and

the date of expiration or the date of collection, whichever is applicable.

**§ 606.170 Adverse reaction file.**

(a) Records shall be maintained of any reports of complaints of adverse reactions regarding each unit of blood or blood product arising as a result of blood collection or transfusion. A thorough investigation of each reported adverse reaction shall be made. A written report of the investigation of adverse reactions, including conclusions and followup, shall be prepared and maintained as part of the record for that lot or unit of final product by the collecting or transfusing facility. When it is determined that the product was at fault in causing a transfusion reaction, copies of all such written reports shall be forwarded to and maintained by the manufacturer or collecting facility.

(b) When a complication of blood collection or transfusion is confirmed to be fatal, the Director, Bureau of Biologics, shall be notified by telephone or telegraph as soon as possible; a written report of the investigation shall be submitted to the Director, Bureau of Biologics, within 7 days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.

2. In Part 640 by adding a new § 640.27 to Subpart C to read as follows:

**§ 640.27 Emergency provisions.**

The use of the plateletpheresis procedure to obtain a product for a specific recipient may be at variance with §§ 640.21(c) and 640.22(c): *Provided*, That: (a) A licensed physician has determined that the recipient must be transfused with the platelets from a specific donor, and (b) the plateletpheresis procedure is performed under the supervision of a qualified licensed physician who is aware of the health status of the donor and the physician has certified in writing that the donor's health permits plateletpheresis.

*Effective date.* This regulation shall be effective December 18, 1975.

(Secs. 201, 501, 502, 510, 701, 52 Stat. 1040-1042 as amended, 1049-1051 as amended by 76 Stat. 780, 1055-1056 as amended, 76 Stat. 794 as amended, and sec. 301 of Pub. L. 87-781 (21 U.S.C. 321, 351, 352, 360 and note, 371)), the Public Health Service Act (secs. 351 and 361, 58 Stat. 702 and 703 amended (42 U.S.C. 262 and 264)), and the Administrative Procedure Act (secs. 4 and 10, 60 Stat. 238 and 243, as amended (5 U.S.C. 553, 702, 703, 704)).

Dated: November 11, 1975.

SAM D. FINE,  
Associate Commissioner  
for Compliance.

[FR Doc. 75-31015 Filed 11-17-75; 8:45 am]